1010521實證醫學月會

內分泌新陳代謝內科 MR3 顏正杰

臨床場景(clinical scenario)分析

- 51-year-old male patient, no underlying
- General malaise, polydipsia and polyuria 1 week
- Admitted for hyperglycemia(1512)
- TG: 1187, T-CHOL: 257, HDL: 30, LDL: 58.4
- No triopathy after examination
- Fenolip 200mg QD was given

提出background questions

- What is diabetes related hyperlipidemia ?
- Mechanism of fibrates ?

What is diabetes related hyperlipidemia

- Hyperlipidemia is association with insulin resistance in patients with type 2 diabetes mellitus
- Hyperinsulinemia are associated with hypertriglyceridemia, low serum high-density lipoprotein cholesterol concentrations and slight increased or normal low-density lipoprotein cholesterol concentration

Mechanism of fibrates

Two factors for fibrate-induced triglycerides fall

- Reduced hepatic secretion of VLDL
- Facilitated clearance of TG-enriched lipoproteins by stimulation of lipoprotein lipase activity

Three mechanisms for fibrate-induced HDL elevation

- Direct stimulation HDL apo A-I and A-II synthesis, which facilitates reverse cholesterol transport
- Increased transfer of apo A-I and other surface components, in order to diminished cholesterol transfer from HDL to VLDL
- Less inhibition by VLDL (due to the reduction in concentration) on hepatic apo A-I synthesis

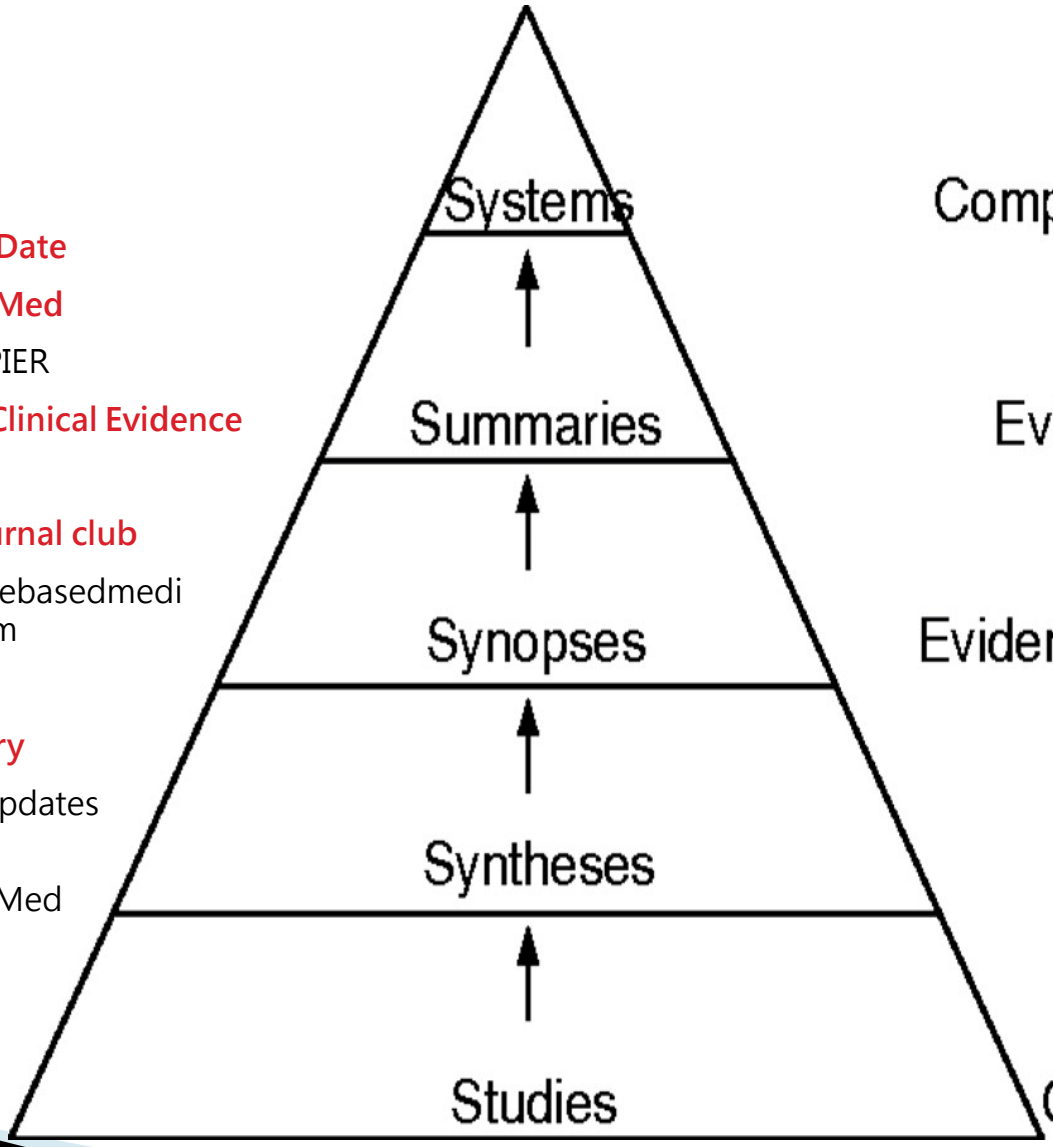
提出foreground questions及提出此問題的理由

問題描述及提出此問題的理由	
P	Diabetic patients
I	Fibrates usage
C	Placebo usage
O	Cardiovascular complications
T	Not confined

搜尋最有用的資料

The "5S" levels of organisation of evidence from healthcare research

Brian Haynes, R Evid Based Med 2006;11:162-164



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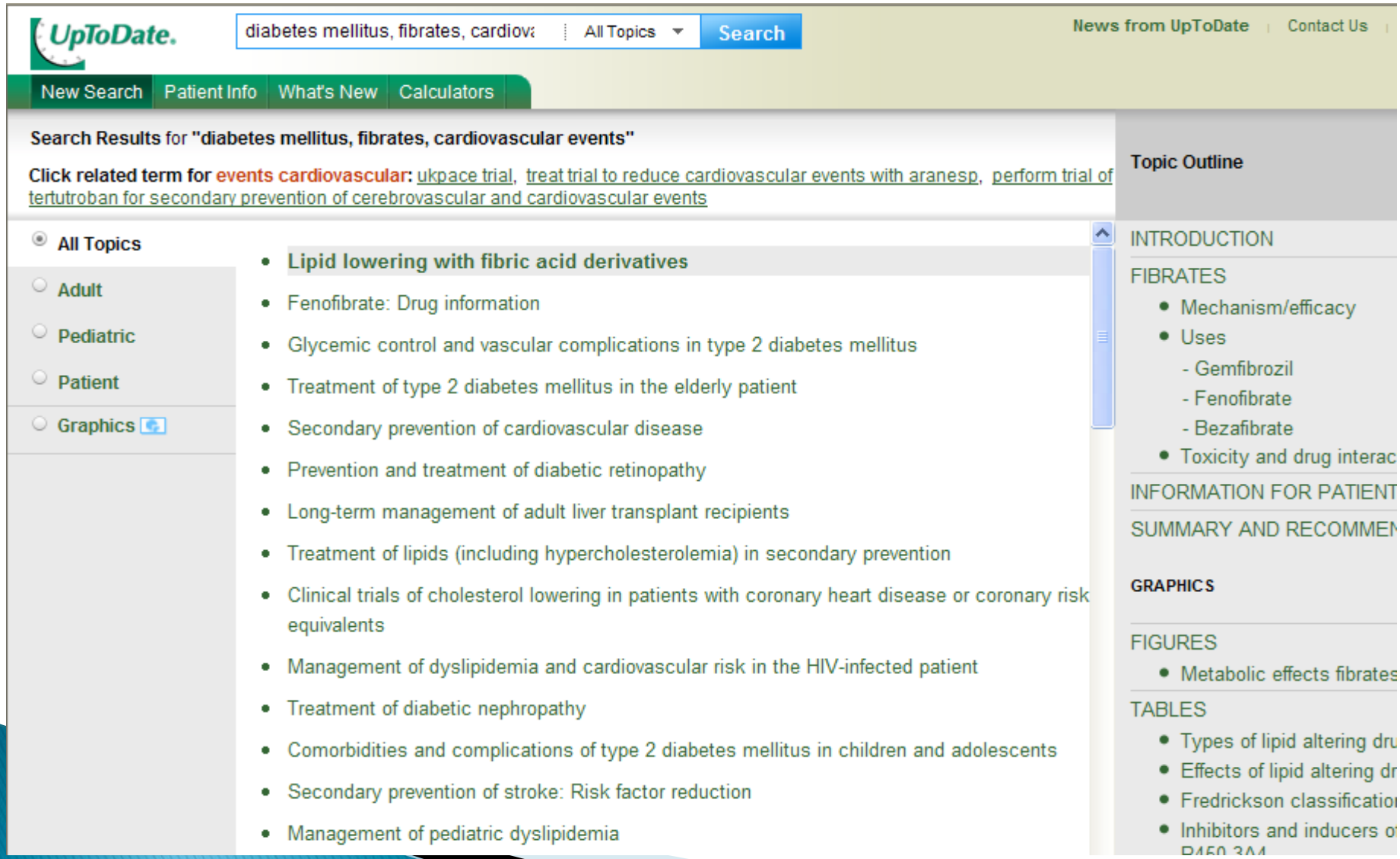
搜尋summary-1

- Key word:
  DM(diabetes mellitus), fibrates, cardiovascular complications

- Search results:
  Lipid lowering with fibric acid derivatives

搜尋結果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Lipid lowering with fibric acid derivatives
Fenofibrate: Drug information
Glycemic control and vascular complications in type 2 diabetes mellitus
Treatment of type 2 diabetes mellitus in the elderly patient
Secondary prevention of cardiovascular disease
Prevention and treatment of diabetic retinopathy
Long-term management of adult liver transplant recipients
Treatment of lipids (including hypercholesterolemia) in secondary prevention
Clinical trials of cholesterol lowering in patients with coronary heart disease or coronary risk equivalents
Management of dyslipidemia and cardiovascular risk in the HIV-infected patient
Treatment of diabetic nephropathy
Comorbidities and complications of type 2 diabetes mellitus in children and adolescents
Secondary prevention of stroke: Risk factor reduction
Management of pediatric dyslipidemia
Topic Outline
INTRODUCTION
FIBRATES
Mechanism/efficacy
Uses
- Gemfibrozil
- Fenofibrate
- Bezafibrate
Toxicity and drug interac
INFORMATION FOR PATIENT
SUMMARY AND RECOMMEN
GRAPHICS
FIGURES
Metabolic effects fibrates
TABLES
Types of lipid altering dru
Effects of lipid altering dr
Fredrickson classificatio
Inhibitors and inducers o

搜尋到的文章內容

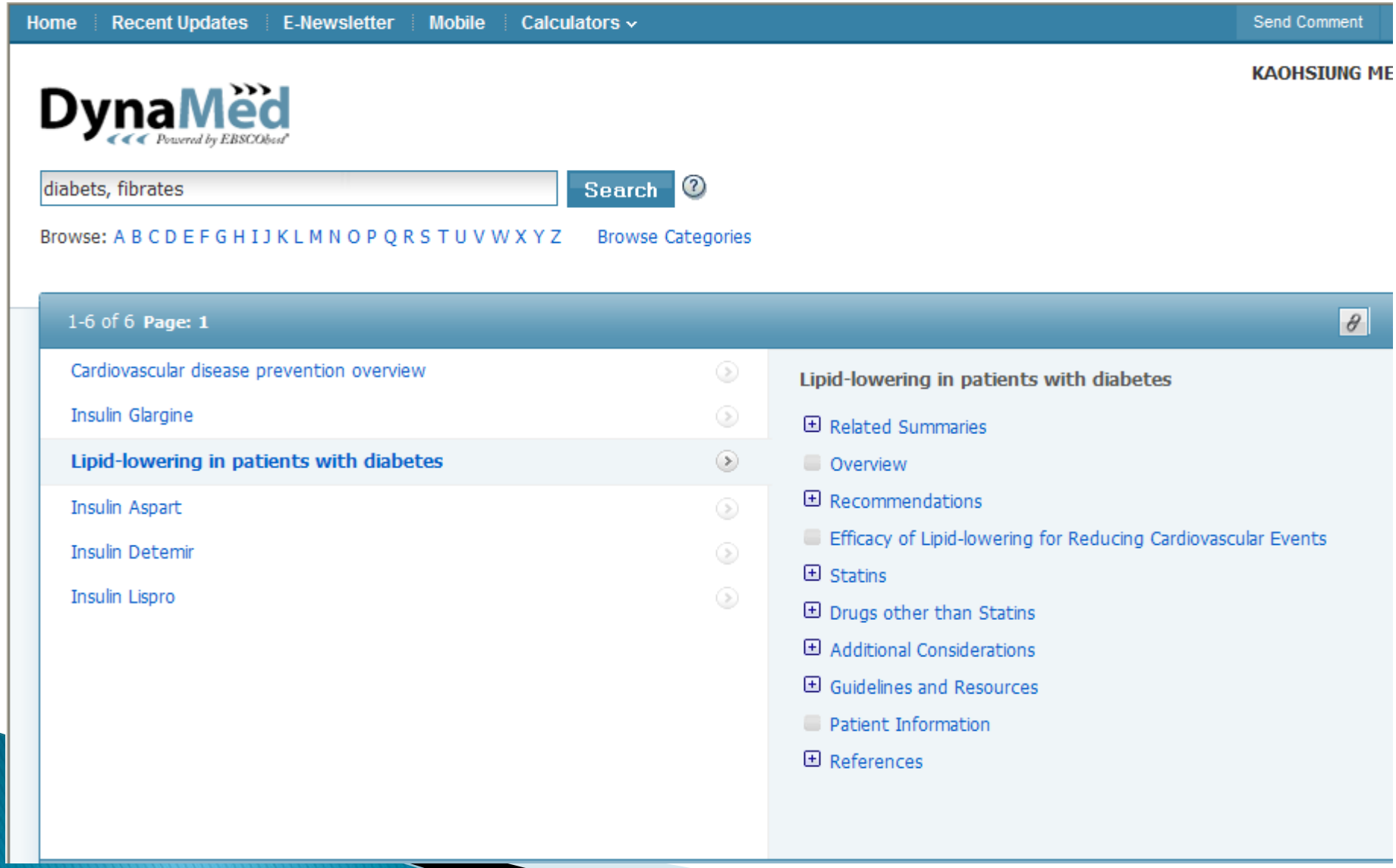
Title of article	Lipid lowering with fibric acid derivatives
Evidence level	1a and 1b
Content	Fibrates may have less-favorable effects on clinical cardiovascular outcomes than statins or niacin Fibrates have primarily shown reductions in cardiovascular events in subsets of patients with high triglycerides (above 200 mg/dl) or low HDL-cholesterol (below 40 mg/dL) and multiple characteristics of the metabolic syndrome Fibrate therapy even harm on the outcome of all-cause mortality due to an increase in noncardiovascular mortality

搜尋summary-2

- Key word:
  DM(diabetes mellitus), fibrates, cardiovascular complications

- Search results:
  Lipid-lowering in patient with diabetes

搜尋結果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Cardiovascular disease prevention overview
Insulin Glargine
Lipid-lowering in patients with diabetes
Insulin Aspart
Insulin Detemir
Insulin Lispro
Lipid-lowering in patients with diabetes
Related Summaries
Overview
Recommendations
Efficacy of Lipid-lowering for Reducing Cardiovascular Events
Statins
Drugs other than Statins
Additional Considerations
Guidelines and Resources
Patient Information
References

搜尋到的文章內容 DynaMed

Title of article	Lipid-lowering in patient with diabetes
Evidence level	1b
Content	Gemfibrozil associated with nonsignificant reduction in coronary heart disease incidence in men with diabetes in primary prevention trial Fenofibrate in patients with diabetes may reduce risk for myocardial infarction but not coronary mortality Fenofibrate does not appear to reduce rate of silent MI but may reduce risk of subsequent cardiovascular event after silent MI Fenofibrate 200 mg/day might reduce angiographic progression of CAD Bezafibrate may reduce incidence of probable ischemic events on ECG in patients with diabetes

搜尋summary-3

- Key word:
  Diabetes, fibrates

- Search results:
  Treating dyslipidemia in people with diabetes

ClinicalEvidence

搜尋結果


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Systematic Reviews (1)
Citations
Guidelines
Patient information
EBM
Other
Systematic review
Intervention - Treating dyslipidaemia in people with diabetes - Diabetes: managing dyslipidaemia
Fibrates
Show all 1 results (may be slow)...

搜尋到的文章內容 ClinicalEvidence

Title of article	Treating dyslipidemia in people with diabetes
Evidence level	1a and 1b
Content	**Cardiovascular events** *Bezafibrate compared with placebo* Bezafibrate may be more effective at reducing CHD event rates at 3 years in people with type 2 diabetes and no clinical history of CVD (low-quality evidence). *Gemfibrozil compared with placebo* Gemfibrozil may be more effective at preventing primary and secondary major coronary events in men with type 2 diabetes (very low-quality evidence). *Fenofibrate compared with placebo* Fenofibrate may be no more effective at reducing total CVD events (first occurrence of non-fatal MI or death from coronary heart disease) in people with type 2 diabetes (low-quality evidence).

搜尋synopses

- Key word:
  Diabetes, fibrates, cardiovascular

- Search results: 2/9
  (1) Long-term fenofibrate therapy did not reduce major coronary events but may reduce total CVD events in type 2 diabetes mellitus
  (2) Lipid-lowering agents reduce cardiovascular events in type 2 diabetes

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搜尋結果

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diabetes, fibrates, cardiovascular Search

Search Help

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2010 - **Fenofibrate** plus simvastatin did not prevent major CV ...

2010 - Intensive blood pressure control did not prevent major ...

2005 - Long-term **fenofibrate** therapy did not reduce major ...

2010 - Intensifying glucose control and adding **fenofibrate** to ...

2010 - Review: **Fibrates** reduce risk for **cardiovascular** ...

2004 - Review: Lipid-lowering agents reduce **cardiovascular** ...

2005 - Review: Mixed signals from trials concerning ...

2003 - Atorvastatin reduced coronary and stroke events in ...

2004 - Cholesterol lowering with simvastatin reduced stroke in ...

搜尋到的文章內容 ACP Journal Club®

Title of article	Long-term fenofibrate therapy did not reduce major coronary events but may reduce total CVD events in type 2 diabetes mellitus
Evidence level	1b
Content	In patients with type 2 diabetes mellitus, long-term fenofibrate therapy did not reduce major coronary events but may reduce total cardiovascular disease events

Fenofibrate vs placebo in patients with type 2 diabetes at median 5 years†

Outcomes	Fenofibrate	Placebo	RRR (95% CI)	NNT (CI)
Nonfatal MI or CHD mortality	5.0%	6.0%	11% (−5 to 24)	Not significant
CVD events	13%	14%	10% (1 to 19)	70 (36 to 1056)
Nonfatal MI	3.0%	4.0%	24% (6 to 38)	101 (58 to 404)
Revascularization	8.0%	10%	19% (8 to 29)	55 (34 to 136)

搜尋到的文章內容 ACP Journal Club®

Title of article	Lipid-lowering agents reduce cardiovascular events in type 2 diabetes
Evidence level	1a
Content	In patients with type 2 diabetes mellitus (with or without coronary artery disease), lipid-lowering agents reduce cardiovascular disease events.

Lipid-lowering agents vs control for cardiovascular disease events in patients with type 2 diabetes*

Category	Number of trials	Weighted event rates		RRR (95% CI)	NNT (CI)
		Lipid-lowering agents	Control†		
Primary prevention‡	6§	10%	13%	22% (11 to 33)	35 (25 to 100) for 4.3 y
Secondary prevention‖	8	28%	35%	24% (7 to 41)	14 (9 to 36) for 4.9 y

搜尋synthesis

- Key words:
  Diabetes, fibrates, cardiovascular complications (coronary artery disease, myocardial infarction)

- Search results:
  No compatible search

搜尋結果

Search Results

Show Results in:
Cochrane Reviews [407] | Other Reviews [811] | Trials [34700] | Methods Studies [381] | Technology Assessments [386] | Economic Evaluations [561] | Cochrane Grou

There are **407** results out of **7227 records** for: "**DIABETES, FIBRATES, CARDIOVASCULAR** in **Title, Abstract or Keywords** in **Cochrane Database of Systematic Reviews**"

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☐ Oral anti-diabetic agents for women with pre-existing diabetes mellitus/impaired glucose tolerance or previous gestational diabetes mellitus
Joanna Tieu, Suzette Coat, William Hague, Philippa Middleton
February 2011
Review

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There are **46** results out of **7227 records** for: "**DIABETES, FIBRATES, CORONARY ARTERY DISEASE** in **Title, Abstract or Keywords** in **Cochrane Database of Systematic Reviews**"

View: **1-25** | 26-46

Export All Results

Record Information Issue: Current | **All** Restrict to: Reviews | Protocols Sort by: Record Title | Ma

☐ Salicylate for the treatment of Kawasaki disease in children

J Harry Baumer, Samantha Love, Amit Gupta, Linda Haines, Ian K Maconochie, Jaspal S Dua

April 2009

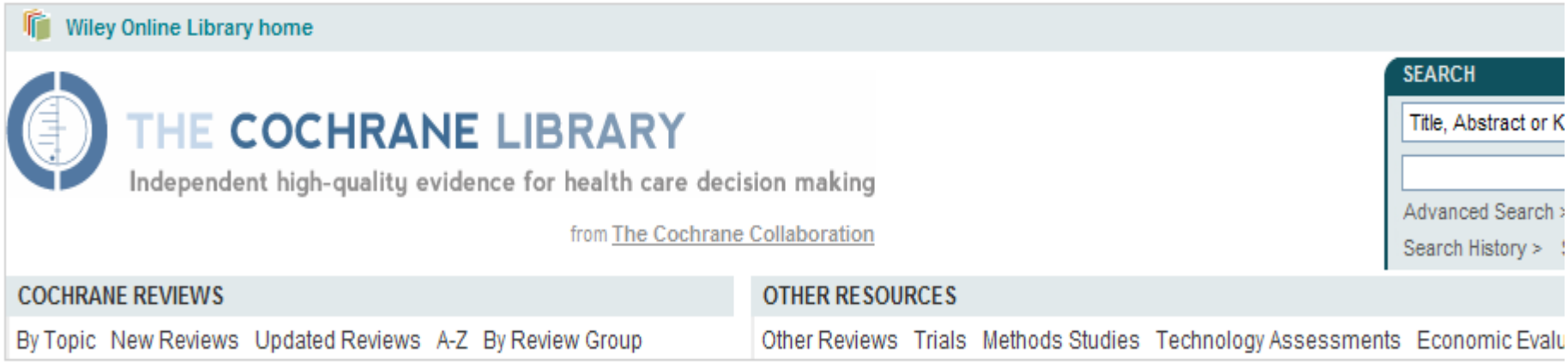
Review

☐ Off-pump versus on-pump coronary artery bypass grafting for ischaemic heart disease

Christian H Møller, Luit Penninga, Jørn Wetterslev, Daniel A Steinbrüchel, Christian Gluud

April 2012

Review



Search Results

Show Results in:
Cochrane Reviews [100] | Other Reviews [355] | Trials [12430] | Methods Studies [207] | Technology Assessments [78] | Economic Evaluations [241] | Cochrane Groups [0]

There are **100** results out of **7227 records** for: "**DIABETES, FIBRATES, MYOCARDIAL INFARCTION** in **Title, Abstract or Keywords** in **Cochrane Database of Systematic Reviews**"

View: **1-25** | 26-50 | 51-75 | 76-100

Export All Results

Record Information — Issue: Current | **All** — Restrict to: Reviews | Protocols — Sort by: Record Title | Ma

☐ Creatine and creatine analogues in hypertension and cardiovascular disease
Deborah L Horjus, Inge Oudman, Gert A van Montfrans, Lizzy M Brewster
November 2011
Review

☐ Early invasive versus conservative strategies for unstable angina and non-ST elevation myocardial infarction in the stent era
Michel R Hoenig, Constantine N Aroney, Ian A Scott
March 2010
Review

搜尋study

- Key words:
  Diabetes mellitus, fibrates, cardiovascular complications

- Search results: 62/226

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US National Library of Medicine
National Institutes of Health

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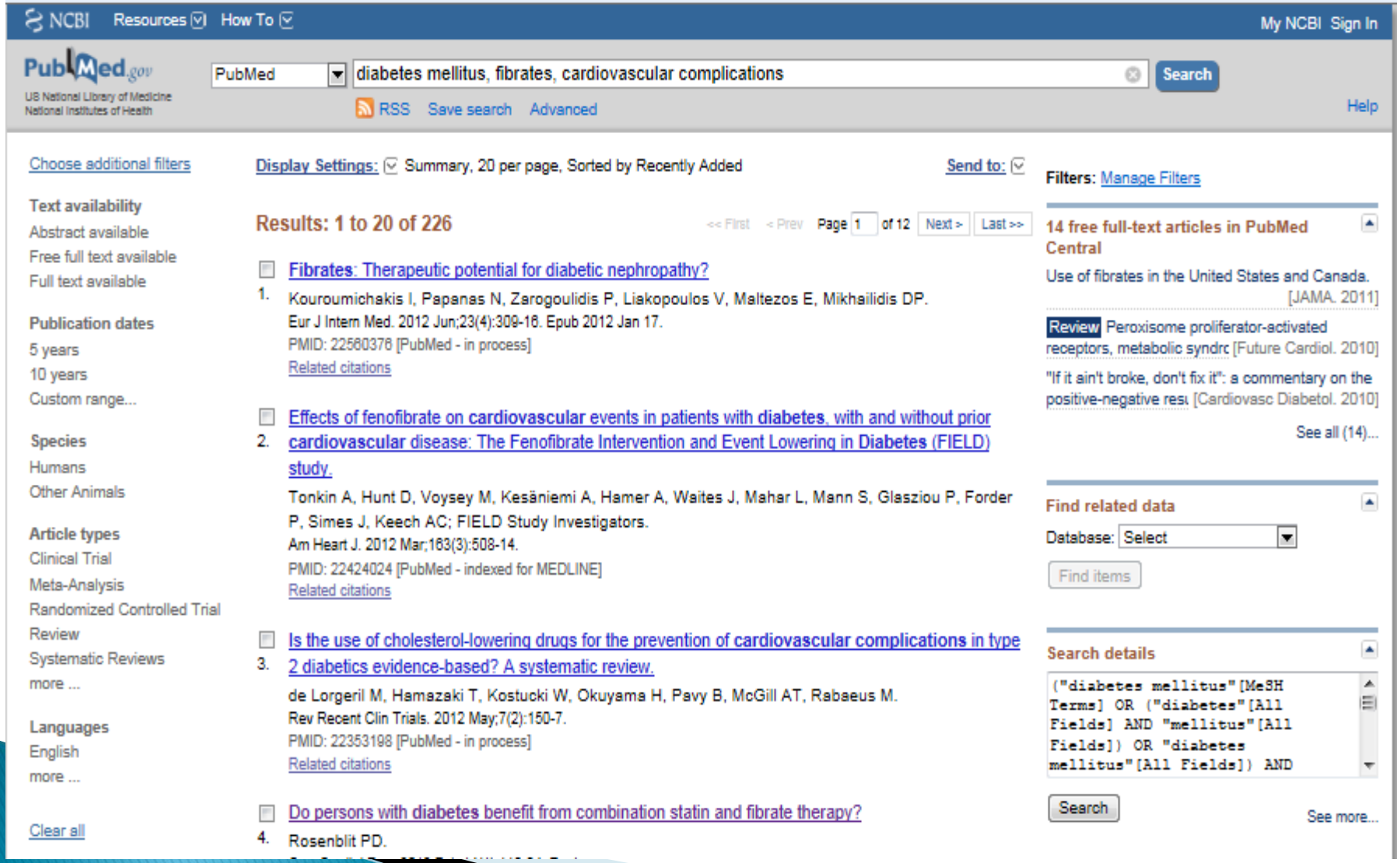
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Meta-Analysis
Randomized Controlled Trial
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more ...
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more ...
Clear all
Display Settings: Summary, 20 per page, Sorted by Recently Added
Send to:
Results: 1 to 20 of 226
<< First < Prev Page 1 of 12 Next > Last >>
Fibrates: Therapeutic potential for diabetic nephropathy?
1. Kouroumichakis I, Papanas N, Zarogoulidis P, Liakopoulos V, Maltezos E, Mikhailidis DP.
Eur J Intern Med. 2012 Jun;23(4):309-16. Epub 2012 Jan 17.
PMID: 22560376 [PubMed - in process]
Related citations
Effects of fenofibrate on cardiovascular events in patients with diabetes, with and without prior cardiovascular disease: The Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study.
2. Tonkin A, Hunt D, Voysey M, Kesäniemi A, Hamer A, Waites J, Mahar L, Mann S, Glasziou P, Forder P, Simes J, Keech AC; FIELD Study Investigators.
Am Heart J. 2012 Mar;163(3):508-14.
PMID: 22424024 [PubMed - indexed for MEDLINE]
Related citations
Is the use of cholesterol-lowering drugs for the prevention of cardiovascular complications in type 2 diabetics evidence-based? A systematic review.
3. de Lorgeril M, Hamazaki T, Kostucki W, Okuyama H, Pavy B, McGill AT, Rabaeus M.
Rev Recent Clin Trials. 2012 May;7(2):150-7.
PMID: 22353198 [PubMed - in process]
Related citations
Do persons with diabetes benefit from combination statin and fibrate therapy?
4. Rosenblit PD.
Filters: Manage Filters
14 free full-text articles in PubMed Central
Use of fibrates in the United States and Canada. [JAMA. 2011]
Review Peroxisome proliferator-activated receptors, metabolic syndrc [Future Cardiol. 2010]
"If it ain't broke, don't fix it": a commentary on the positive-negative resu [Cardiovasc Diabetol. 2010]
See all (14)...
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("diabetes mellitus"[MeSH Terms] OR ("diabetes"[All Fields] AND "mellitus"[All Fields]) OR "diabetes mellitus"[All Fields]) AND
Search
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搜尋到的文章內容

Effects of long-term fenofibrate therapy on cardiovascular events in 9795 people with type 2 diabetes mellitus (the FIELD study): randomised controlled trial

Lancet 2005; 366: 1849–61

Fenofibrate Intervention and Event Lowering in Diabetes

Home

The FIELD Study

Management committee
Background
Protocol
Collaborating sites map

FIELD results

Latest findings 2008
2007 Results
2005 Results
Publications

CONTACTS

NHMRC Clinical Trial Centre
Media contacts
FIELD Press Office

Results of FIELD

New Findings 2008 :

- CTC Press Release
- Abstracts
- Press conference webcast

Findings 2007 :

- CTC Press Release
- The Lancet article
- Press conference webcast

The results of the FIELD trial were reported at the Annual Scientific Sessions of the American Heart Association in Dallas on 14 November and published simultaneously in *The Lancet*.

FIELD has been a double-blind placebo-controlled trial of prevention of coronary heart disease in people with type 2 diabetes. The trial was conducted in Australia, New Zealand and Finland. A feature of the trial is that its wide entry criteria allow the results to be generalised to a population of typical patients with diabetes consulting general practitioners. The trial began recruiting patients in early 1998, and randomly assigned the last of its 9795 participants in November 2000. Its five-year follow-up was completed in October 2005.

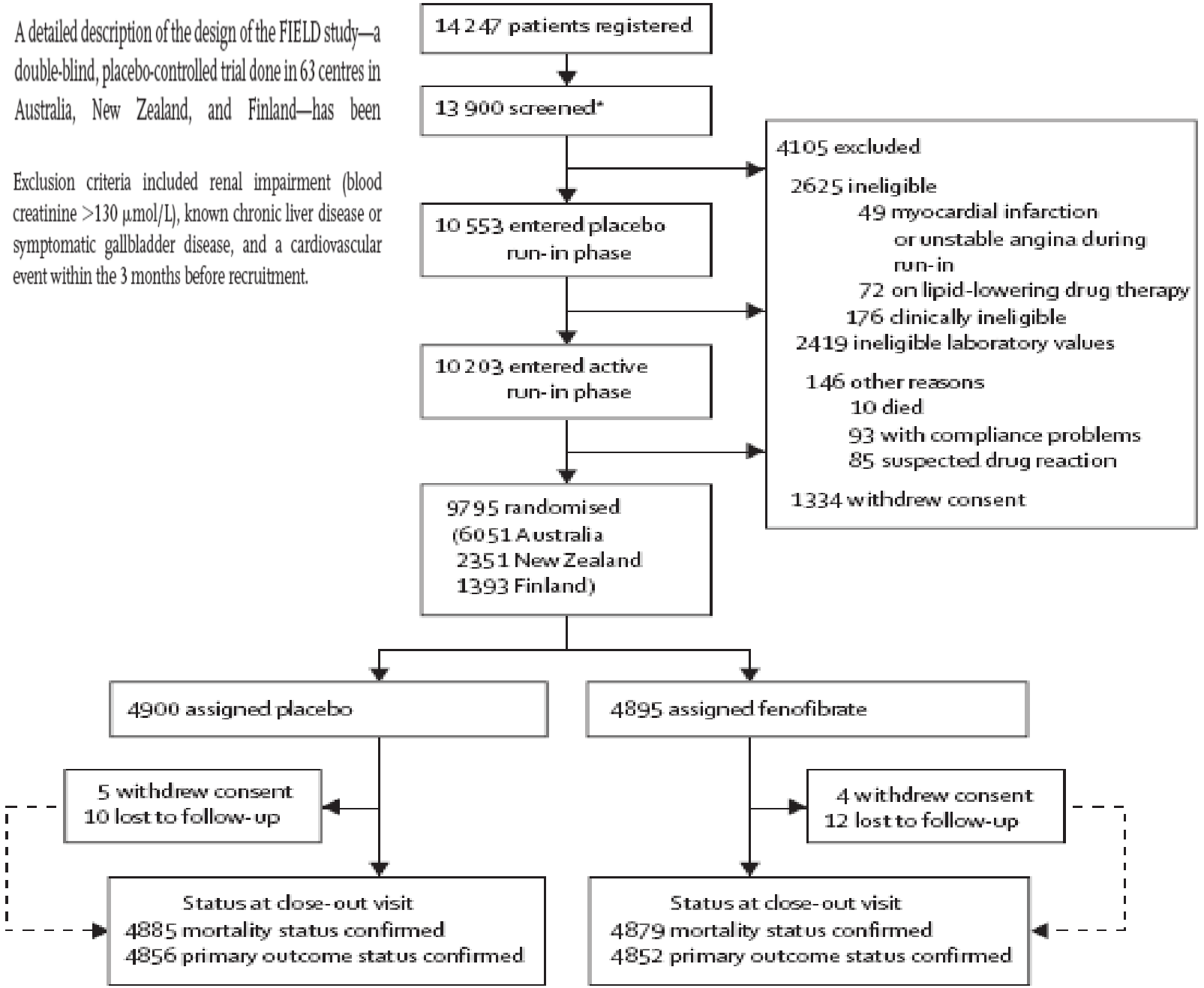
Main eligibility criteria:

- type 2 diabetes mellitus with onset after the age of 35 years
- men and women aged 50–75 years of age
- average total cholesterol 3.0–6.5 mmol/L
- triglycerides/high-density cholesterol ratio of 4.0 or higher, or triglycerides over 1.0 mmol/L

- Diabetes generally have lower HDL-cholesterol and higher TG levels, which are associated with an increased risk of cardiovascular disease
- This pattern of dyslipidmia can be corrected with fibrates. Fibrates is therefore believed a logical treatment for diabetic dyslipidemia. (HHS, VA-HIT, BIP trial, SENDCAP study and DAIS)
- FIELD study is designed to assess the effects on coronary morbidity and mortality of long-term treatment with fenofibrate

A detailed description of the design of the FIELD study—a double-blind, placebo-controlled trial done in 63 centres in Australia, New Zealand, and Finland—has been

Exclusion criteria included renal impairment (blood creatinine >130 μmol/L), known chronic liver disease or symptomatic gallbladder disease, and a cardiovascular event within the 3 months before recruitment.



*347 patients accepted an invitation but did not attend.

	Placebo (n=4900)	Fenofibrate (n=4895)
General characteristics		
Male	3067 (63%)	3071 (63%)
White	4559 (93%)	4534 (93%)
Age at visit 1 (years, mean [SD])	62·2 (6·9)	62·2 (6·8)
Diabetes duration (years, median [IQR])*	5 (2–10)	5 (2–10)
Body-mass index (kg/m², median [IQR])	29·8 (26·7–33·4)	29·8 (26·8–33·6)
Waist-to-hip ratio (median [IQR])	0·94 (0·88–0·98)	0·94 (0·88–0·98)
Blood pressure (mm Hg, mean [SD])		
Systolic	141 (15)	140 (15)
Diastolic	82 (9)	82 (9)
Current smoker	460 (9%)	462 (9%)
Ex-smoker	2490 (51%)	2454 (50%)
Clinical history		
Previous cardiovascular disease	1063 (22%)	1068 (22%)
Myocardial infarction	255 (5%)	230 (5%)
Stroke	182 (4%)	164 (3%)
Angina	588 (12%)	600 (12%)
Peripheral vascular disease	354 (7%)	357 (7%)
Coronary revascularisation (CABG or PTCA)	168 (3%)	195 (4%)
History of hypertension*	2768 (56%)	2776 (57%)
Microvascular disease*	998 (20%)	1026 (21%)
Retinopathy*	412 (8%)	402 (8%)
Neuropathy*	687 (14%)	707 (14%)
Nephropathy*	135 (3%)	144 (3%)

Laboratory data†‡		
Total cholesterol (mmol/L, mean [SD])	5·03 (0·71)	5·04 (0·69)
LDL cholesterol (mmol/L, mean [SD])	3·07 (0·66)	3·07 (0·64)
HDL cholesterol (mmol/L, mean [SD])	1·10 (0·26)	1·10 (0·26)
Triglycerides (mmol/L, median [IQR])	1·73 (1·34–2·30)	1·74 (1·34–2·34)
HbA1c (%, median [IQR])	6·9 (6·1–7·8)	6·9 (6·1–7·8)
Plasma creatinine (μmol/L, mean [SD])	77·4 (15·7)	77·7 (15·9)
Homocysteine (μmol/L, median [IQR])	9·6 (8·0–11·4)	9·5 (7·9–11·6)
Dyslipidaemia§	1824 (37%)	1886 (39%)
Microalbuminuria¶	925 (19%)	925 (19%)
Macroalbuminuria¶	157 (3%)	156 (3%)
Baseline cardiovascular medication		
Any antithrombotic	1569 (32%)	1574 (32%)
Aspirin	1455 (30%)	1448 (30%)
Other	170 (4%)	165 (3%)
Angiotensin-converting enzyme inhibitor	1725 (35%)	1716 (35%)
Angiotensin II receptor antagonist	265 (5%)	280 (6%)
β blocker	748 (15%)	757 (15%)
Calcium antagonist	983 (20%)	1013 (21%)
Nitrate	306 (6%)	260 (5%)
Diuretic	780 (16%)	798 (16%)
Baseline blood-glucose-lowering medication		
Diet alone	1284 (26%)	1258 (26%)
Metformin alone	823 (17%)	828 (17%)
Sulfonylurea alone	799 (16%)	809 (17%)
Metformin+sulfonylurea	1196 (24%)	1207 (25%)
Other oral agent	10 (<1%)	9 (<1%)
Metformin and/or sulfonylurea+other oral agent	100 (2%)	93 (2%)
Insulin alone	286 (6%)	283 (6%)
Insulin+oral agent	402 (8%)	408 (8%)

	Plasma concentrations at baseline (mean [SD])		Absolute (mmol/L) and relative (%) differences between treatment groups in plasma lipid concentrations after randomisation*				Plasma concentrations at study close (mean [SD])	
	Placebo	Fenofibrate	4 months	1 year	2 years	Study close	Placebo	Fenofibrate
Full cohort (fenofibrate n=4895, placebo n=4900)								
Total cholesterol	5·03 (0·71)	5·04 (0·69)	−0·58 (−11·4%)	−0·58 (−11·6%)	−0·56 (−11·1%)	−0·33 (−6·9%)	4·56 (0·90)	4·23 (0·78)
LDL cholesterol	3·07 (0·66)	3·07 (0·64)	−0·39 (−12·0%)	−0·38 (−11·9%)	−0·36 (−11·7%)	−0·17 (−5·8%)	2·60 (0·78)	2·43 (0·65)
HDL cholesterol	1·10 (0·26)	1·10 (0·26)	0·05 (5·1%)	0·05 (4·5%)	0·04 (3·5%)	0·01 (1·2%)	1·12 (0·29)	1·13 (0·30)
Triglycerides	1·93 (0·88)	1·95 (0·87)	−0·56 (−28·6%)	−0·58 (−30·2%)	−0·52 (−27·4%)	−0·41 (−21·9%)	1·87 (0·96)	1·47 (0·78)
Started other lipid-lowering therapy (fenofibrate n=944, placebo n=1776)								
Total cholesterol	5·2 (0·67)	5·25 (0·69)	−0·42 (−8·0%)	−0·39 (−7·6%)	−0·33 (−6·5%)	−0·08 (−1·6%)	4·12 (0·88)	3·98 (0·85)
LDL cholesterol	3·31 (0·63)	3·23 (0·64)	−0·24 (−6·6%)	−0·19 (−5·5%)	−0·15 (−4·6%)	0·02 (0·7%)	2·18 (0·74)	2·13 (0·66)
HDL cholesterol	1·08 (0·25)	1·03 (0·24)	0·05 (4·6%)	0·03 (2·8%)	0·01 (1·7%)	−0·01 (−0·5%)	1·12 (0·28)	1·05 (0·29)
Triglycerides	2·08 (0·99)	2·22 (0·99)	−0·54 (−24·6%)	−0·55 (−24·8%)	−0·45 (−21·0%)	−0·24 (−10·9%)	1·84 (0·97)	1·74 (0·96)
Did not start other lipid-lowering therapy (fenofibrate n=3951, placebo n=3124)								
Total cholesterol	4·87 (0·68)	4·99 (0·69)	−0·63 (−12·5%)	−0·66 (−13·1%)	−0·68 (−13·4%)	−0·66 (−13·1%)	4·82 (0·80)	4·29 (0·74)
LDL cholesterol	2·93 (0·64)	3·03 (0·64)	−0·44 (−13·6%)	−0·45 (−14·3%)	−0·48 (−15·3%)	−0·46 (−14·7%)	2·84 (0·70)	2·50 (0·63)
HDL cholesterol	1·11 (0·27)	1·11 (0·26)	0·05 (5·1%)	0·05 (4·8%)	0·04 (4·0%)	0·02 (2·1%)	1·13 (0·29)	1·15 (0·30)
Triglycerides	1·85 (0·81)	1·89 (0·83)	−0·57 (−29·6%)	−0·60 (−31·6%)	−0·55 (−29·1%)	−0·51 (−27·3%)	1·88 (0·95)	1·41 (0·72)

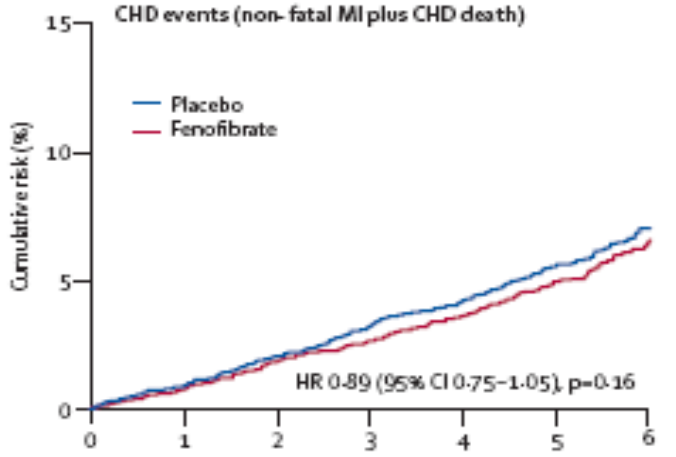
*Fenofibrate minus placebo. $p<0.05$ for all differences between groups at every timepoint shown, except in patients who started other lipid-lowering therapy, for HDL cholesterol and LDL cholesterol at study close.

	Placebo (n=4900)		Fenofibrate (n=4895)		HR (95% CI)	Log-rank p
	Number (%)*	Rate/1000 person-years at risk	Number (%)*	Rate/1000 person-years at risk		
Primary outcome						
Coronary events	288 (6%)	11·7	256 (5%)	10·4	0·89 (0·75–1·05)	0·16
Coronary heart disease mortality	93 (2%)	3·7	110 (2%)	4·4	1·19 (0·90–1·57)	0·22
Non-fatal myocardial infarction	207 (4%)	8·4	158 (3%)	6·4	0·76 (0·62–0·94)	0·010
Secondary outcome						
Total cardiovascular disease events	683 (14%)	29·0	612 (13%)	25·8	0·89 (0·80–0·99)	0·035
Cardiovascular disease mortality	127 (3%)	5·1	140 (3%)	5·6	1·11 (0·87–1·41)	0·41
Total mortality	323 (7%)	12·9	356 (7%)	14·2	1·11 (0·95–1·29)	0·18
Total stroke	175 (4%)	7·1	158 (3%)	6·4	0·90 (0·73–1·12)	0·36
Non-haemorrhagic stroke	158 (3%)	6·4	144 (3%)	5·8	0·91 (0·73–1·14)	0·43
Coronary revascularisation	364 (7%)	15·0	290 (6%)	11·9	0·79 (0·68–0·93)	0·003
All revascularisation†	471 (10%)	19·7	380 (8%)	15·8	0·80 (0·70–0·92)	0·001

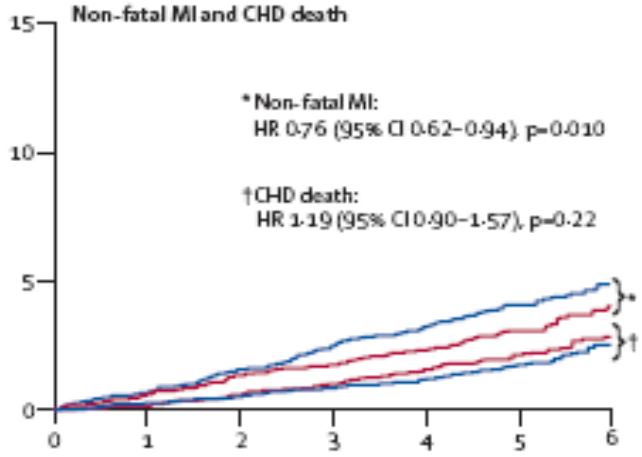
*Only first event for each patient counted in each row. †Includes coronary, carotid, and all other peripheral revascularisation.

	Placebo (number)	Fenofibrate (number)
Coronary	93	110
Fatal myocardial infarction	23	22
Sudden cardiac death	54	70
Death in hospital (possible myocardial infarction)	2	3
Heart failure	11	13
Death after coronary revascularisation	2	2
Certified other coronary	1	0
Vascular	34	30
Non-coronary cardiac	4	8
Stroke	24	15
Pulmonary embolism	1	4
Other vascular	5	3
Total	127	140

Webtable 1: **Deaths from cardiovascular causes**

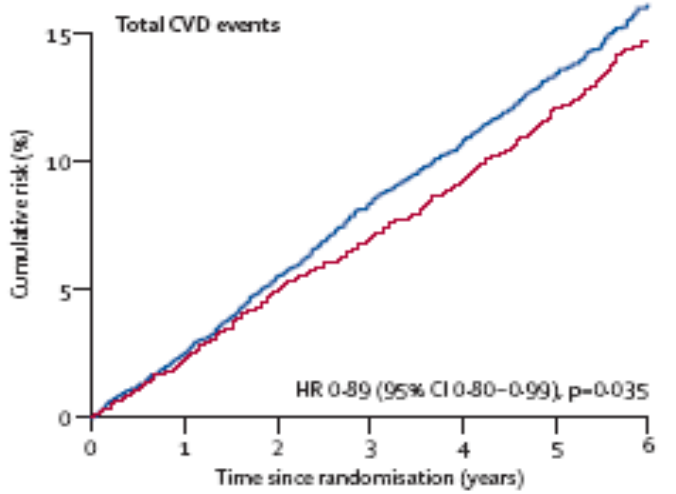


Numbers at risk							
Placebo	4900	4835	4741	4646	4547	2541	837
Fenofibrate	4895	4837	4745	4664	4555	2553	850

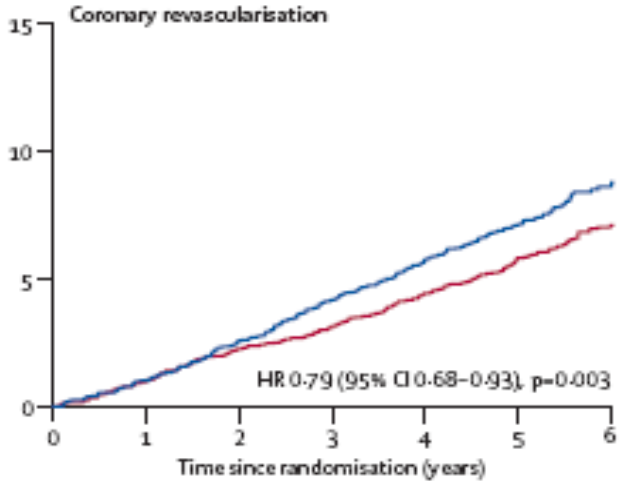


Numbers at risk: non-fatal MI							
Placebo	4900	4835	4741	4646	4547	2541	837
Fenofibrate	4895	4837	4745	4664	4555	2553	850

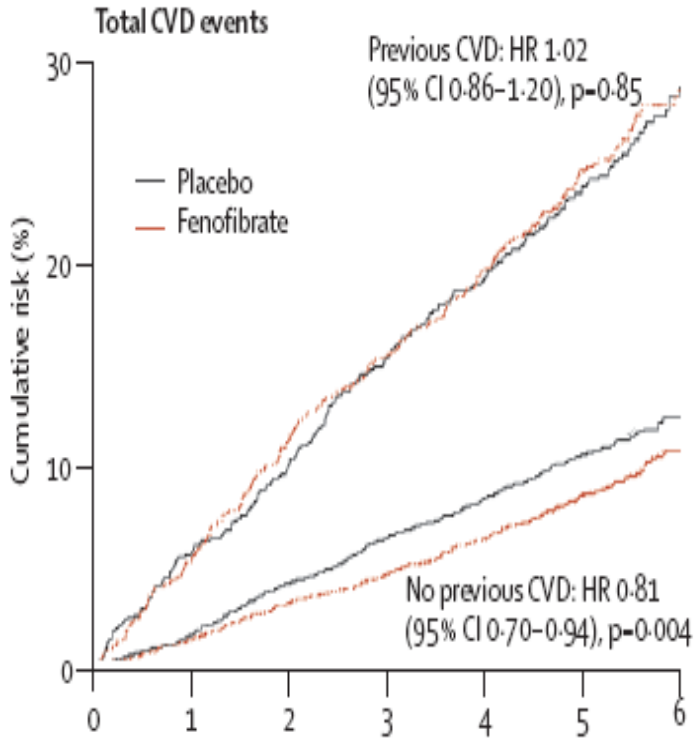
Numbers at risk: CHD death							
Placebo	4900	4866	4815	4759	4689	2651	882
Fenofibrate	4895	4866	4806	4740	4649	2638	889



Numbers at risk							
Placebo	4900	4762	4586	4419	4257	2340	750
Fenofibrate	4895	4771	4604	4669	4305	2370	775



	4900	4818	4693	4567	4423	2457	796
	4895	4817	4698	4592	4445	2476	820

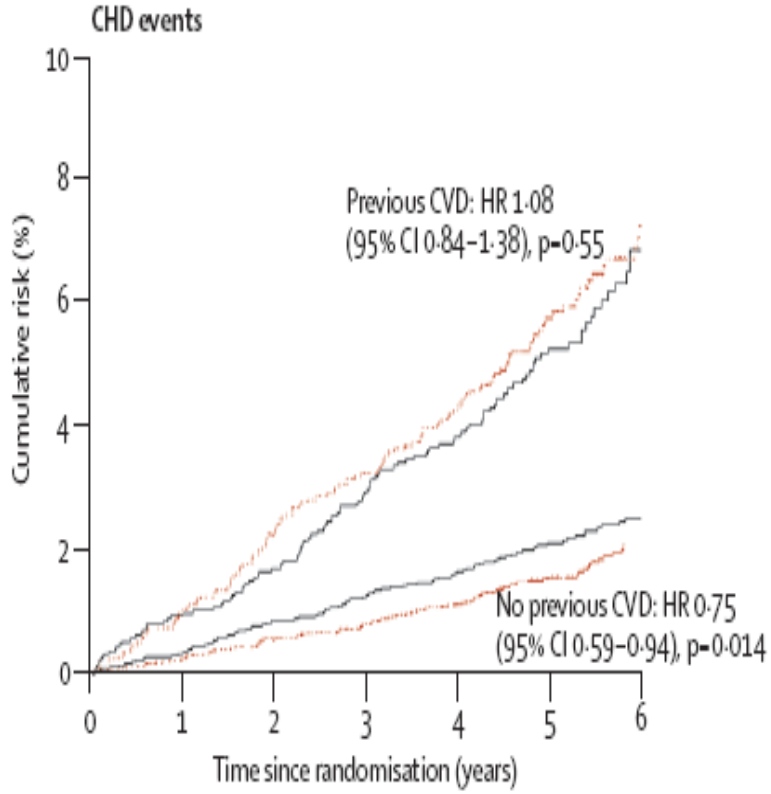


Numbers at risk: previous CVD

Placebo	1063	997	944	881	826	473	178
Fenofibrate	1068	1007	933	879	818	488	175

Numbers at risk: no previous CVD

Placebo	3837	3765	3642	3538	3431	1867	572
Fenofibrate	3827	3764	3671	3590	3489	1882	600

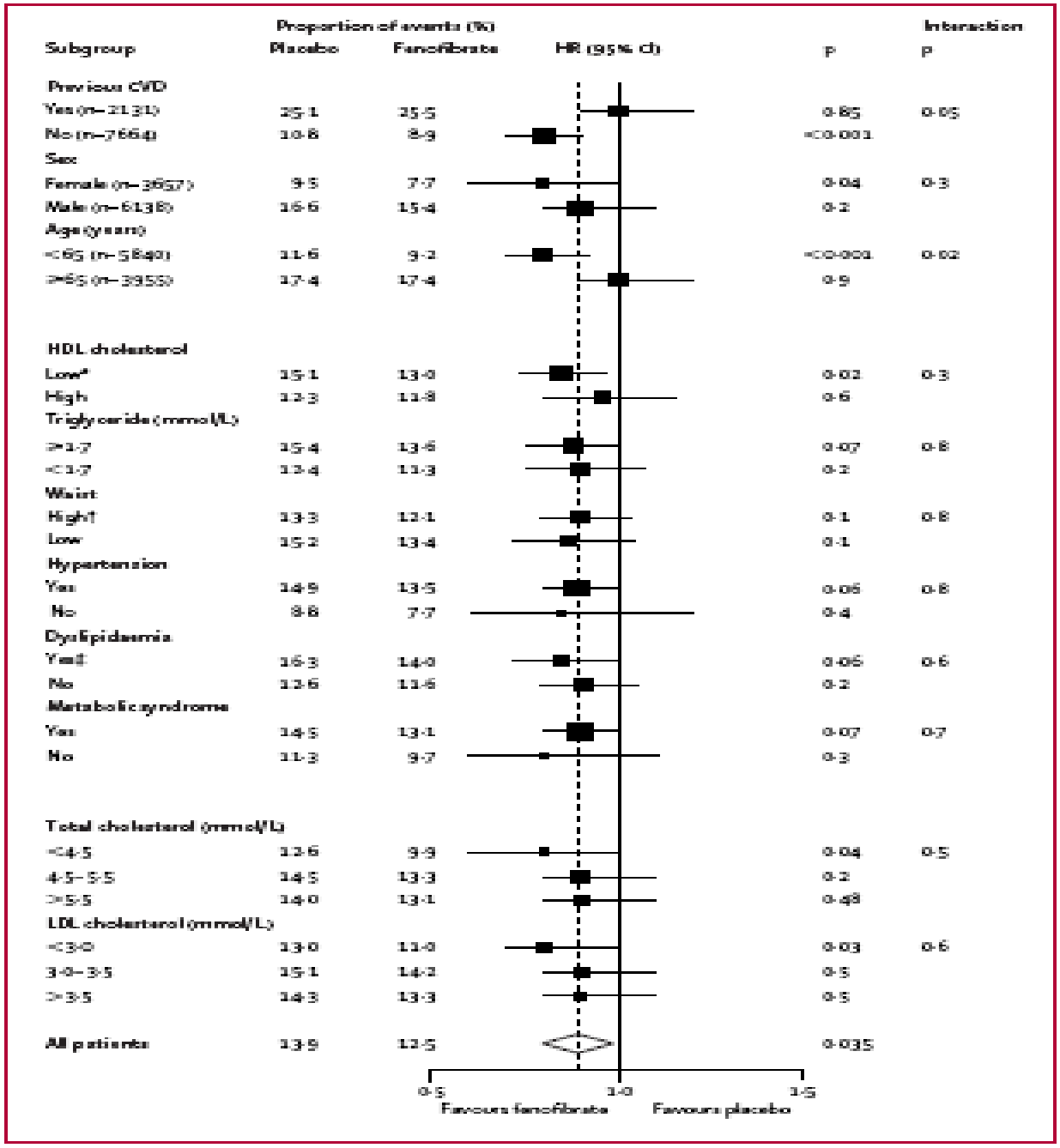


Numbers at risk: previous CVD

Placebo	1063	1034	1009	970	934	555	213
Fenofibrate	1068	1039	1000	967	923	569	216

Numbers at risk: no previous CVD

Placebo	3837	3801	3732	3676	3613	1986	624
Fenofibrate	3827	3798	3745	3697	3632	1984	634


Proportion of events (%)
Subgroup
Placebo
Fenofibrate
HR (95% CI)
p
Interaction p
Previous CVD
Yes (n=2131) 25·1 25·5 0·85 0·05
No (n=7664) 10·8 8·9 <0·001
Sex
Female (n=3657) 9·5 7·7 0·04 0·3
Male (n=6138) 16·6 15·4 0·2
Age (years)
<65 (n=5840) 11·6 9·2 <0·001 0·02
≥65 (n=3955) 17·4 17·4 0·9
HDL cholesterol
Low* 15·1 13·0 0·02 0·3
High 12·3 11·8 0·6
Triglyceride (mmol/L)
≥1·7 15·4 13·6 0·07 0·8
<1·7 12·4 11·3 0·2
Waist
High† 13·3 12·1 0·1 0·8
Low 15·2 13·4 0·1
Hypertension
Yes 14·9 13·5 0·06 0·8
No 8·8 7·7 0·4
Dyslipidaemia
Yes‡ 16·3 14·0 0·06 0·6
No 12·6 11·6 0·2
Metabolic syndrome
Yes 14·5 13·1 0·07 0·7
No 11·3 9·7 0·3
Total cholesterol (mmol/L)
<4·5 12·6 9·9 0·04 0·5
4·5–5·5 14·5 13·3 0·2
≥5·5 14·0 13·1 0·48
LDL cholesterol (mmol/L)
<3·0 13·0 11·0 0·03 0·6
3·0–3·5 15·1 14·2 0·5
≥3·5 14·3 13·3 0·5
All patients 13·9 12·5 0·035
0·5
1·0
1·5
Favours fenofibrate
Favours placebo

	Placebo group (n=4900)		Fenofibrate group (n=4895)	
	Change from baseline (%)	Number (%) at final visit*	Change from baseline (%)	Number (%) at final visit*
Cardiovascular medication				
Any antithrombotic	24·0	2744 (56%)	22·7	2688 (55%)
Aspirin	18·2	2348 (48%)	17·2	2291 (47%)
Other	9·2	622 (13%)	9·1	613 (13%)
Angiotensin-converting enzyme inhibitor	12·7	2348 (48%)	9·8	2197 (45%)
Angiotensin II receptor antagonist	14·8	991 (20%)	13·8	956 (20%)
β blocker	11·0	1290 (26%)	8·6	1179 (24%)
Calcium antagonist	7·1	1335 (27%)	5·4	1277 (26%)
Digoxin	5·6	201 (4%)	5·8	242 (5%)
Diuretic	7·7	1157 (24%)	5·0	1043 (21%)
Nitrate	5·6	577 (12%)	5·8	543 (11%)
Lipid-lowering agent†	36·0	1776 (36%)	19·0	944 (19%)
Blood-glucose-lowering medication				
Oral	9·9	3818 (78%)	9·7	3829 (78%)
Insulin	15·9	1464 (30%)	15·9	1467 (30%)

*Within 3 months of study close. †For this category only, defined as the cumulative number of patients who had used non-study lipid-lowering treatment for more than 3 months at any time. Signficant differences at study close: angiotensin-converting enzyme inhibitors p=0·003, β blockers p=0·011, diuretics p=0·006, digoxin p=0·045, lipid-lowering agents p=<0·0001.

Table 4: **Patients on concominant medication between baseline and study close**

	Placebo (n=4900)	Fenofibrate (n=4895)
Any serious adverse event*		
Death, other than cardiovascular causes	196 (4%)	216 (4%)
Cancer	148 (3%)	168 (3%)
Respiratory disease	16 (<1%)	19 (<1%)
Trauma	12 (<1%)	11 (<1%)
Other	20 (<1%)	18 (<1%)
Non-fatal events*	3346 (68%)	3361 (69%)
Gastrointestinal	927 (19%)	975 (20%)
Cardiac	807 (17%)	727 (15%)
Musculoskeletal	739 (15%)	755 (15%)
Tumour-related†	661 (14%)	643 (13%)
Genitourinary	568 (12%)	607 (12%)
Special senses‡	527 (11%)	499 (10%)
Vascular (non-cardiac)	439 (9%)	418 (9%)
Respiratory	342 (7%)	384 (8%)
Newly diagnosed cancer	373 (8%)	393 (8%)
Colorectal	60 (1%)	67 (1%)
Prostate	59 (1%)	65 (1%)
Other gastrointestinal	49 (1%)	47 (1%)
Respiratory	41 (<1%)	45 (<1%)
Breast	38 (<1%)	37 (<1%)
Urinary	31 (<1%)	24 (<1%)
Clinically important events in <2% of patients*		
Deep-vein thrombosis	48 (1·0%)	67 (1%)
Pulmonary embolism	32 (0·7%)	53 (1%)
Pancreatitis	23 (0·5%)	40 (0·8%)
Myositis	1 (<1%)	2 (<1%)
Rhabdomyolysis	1 (<1%)	3 (<1%)
Renal disease needing dialysis	21 (<1%)	16 (<1%)
Laboratory variable measurements		
Raised alanine aminotransferase		
3–5×upper limit of normal	26 (<1%)	11 (<1%)
>5×upper limit of normal	12 (<1%)	11 (<1%)
Raised creatine phosphokinase		
5–10×upper limit of normal	7 (<1%)	11 (<1%)
>10×upper limit of normal	3 (<1%)	4 (<1%)
Raised creatinine		
>200 µmol/L	48 (1%)	73 (2%)

Data are number (%) *Other than primary and secondary cardiovascular outcomes. †Includes invasive cancers, in-situ cancers, non-melanoma skin cancers, and benign tumours. ‡Includes cataract and other eye and ear conditions.

patients was taking statin therapy. Patients allocated to fenofibrate were at greater risk for pancreatitis than those on placebo, but the numbers were small (23 [0·5%] *vs* 40 [0·8%]; p=0·031). There was also a small increased risk of pulmonary embolism (p=0·022) and deep venous thrombosis (p=0·074) associated with fenofibrate. There

Critical appraisal(嚴格評讀)

Effects of long-term fenofibrate therapy on cardiovascular events in 9795 people with type 2 diabetes mellitus (the FIELD study): randomised controlled trial

Lancet 2005; 366: 1849–61

證據等級: 1b(individual RCT)

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

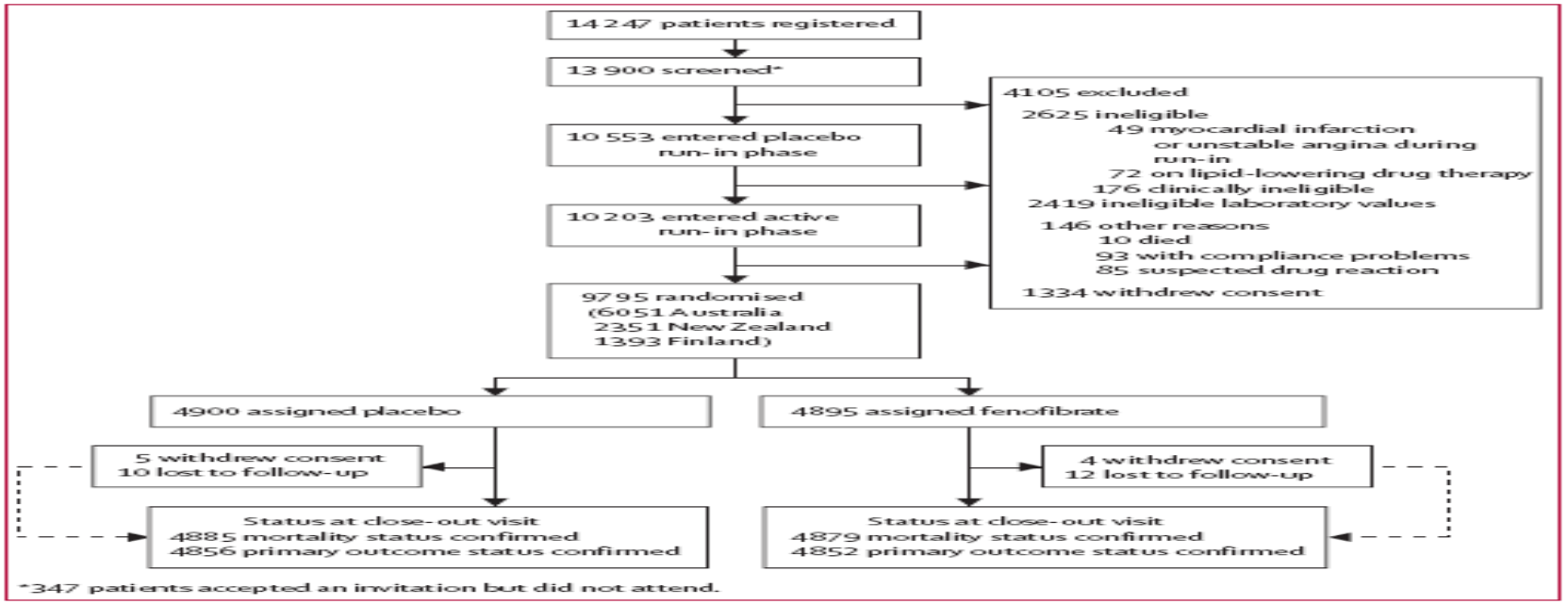
Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998.

Are the results of the trial valid ?

Was the assignment of patients to treatment randomised (是隨機分配嗎) ?

Answer: Yes



Are the results of the trial valid ?

Were the groups similar at the start of the trial (試驗開始時兩組條件是否相似) ?

Answer: **Yes**

	Placebo (n=4900)	Fenofibrate (n=4895)
General characteristics		
Male	3067 (63%)	3071 (63%)
White	4559 (93%)	4534 (93%)
Age at visit 1 (years, mean [SD])	62·2 (6·9)	62·2 (6·8)
Diabetes duration (years, median [IQR])*	5 (2–10)	5 (2–10)
Body-mass index (kg/m², median [IQR])	29·8 (26·7–33·4)	29·8 (26·8–33·6)
Waist-to-hip ratio (median [IQR])	0·94 (0·88–0·98)	0·94 (0·88–0·98)
Blood pressure (mm Hg, mean [SD])		
Systolic	141 (15)	140 (15)
Diastolic	82 (9)	82 (9)
Current smoker	460 (9%)	462 (9%)
Ex-smoker	2490 (51%)	2454 (50%)
Clinical history		
Previous cardiovascular disease	1063 (22%)	1068 (22%)
Myocardial infarction	255 (5%)	230 (5%)
Stroke	182 (4%)	164 (3%)
Angina	588 (12%)	600 (12%)
Peripheral vascular disease	354 (7%)	357 (7%)
Coronary revascularisation (CABG or PTCA)	168 (3%)	195 (4%)
History of hypertension*	2768 (56%)	2776 (57%)
Microvascular disease*	998 (20%)	1026 (21%)
Retinopathy*	412 (8%)	402 (8%)
Neuropathy*	687 (14%)	707 (14%)
Nephropathy*	135 (3%)	144 (3%)
Laboratory data†‡		
Total cholesterol (mmol/L, mean [SD])	5·03 (0·71)	5·04 (0·69)
LDL cholesterol (mmol/L, mean [SD])	3·07 (0·66)	3·07 (0·64)
HDL cholesterol (mmol/L, mean [SD])	1·10 (0·26)	1·10 (0·26)
Triglycerides (mmol/L, median [IQR])	1·73 (1·34–2·30)	1·74 (1·34–2·34)
HbA1c (%, median [IQR])	6·9 (6·1–7·8)	6·9 (6·1–7·8)
Plasma creatinine (μmol/L, mean [SD])	77·4 (15·7)	77·7 (15·9)
Homocysteine (μmol/L, median [IQR])	9·6 (8·0–11·4)	9·5 (7·9–11·6)
Dyslipidaemia§	1824 (37%)	1886 (39%)
Microalbuminuria¶	925 (19%)	925 (19%)
Macroalbuminuria¶	157 (3%)	156 (3%)
Baseline cardiovascular medication		
Any antithrombotic	1569 (32%)	1574 (32%)
Aspirin	1455 (30%)	1448 (30%)
Other	170 (4%)	165 (3%)
Angiotensin-converting enzyme inhibitor	1725 (35%)	1716 (35%)
Angiotensin II receptor antagonist	265 (5%)	280 (6%)
β blocker	748 (15%)	757 (15%)
Calcium antagonist	983 (20%)	1013 (21%)
Nitrate	306 (6%)	260 (5%)
Diuretic	780 (16%)	798 (16%)
Baseline blood-glucose-lowering medication		
Diet alone	1284 (26%)	1258 (26%)
Metformin alone	823 (17%)	828 (17%)
Sulfonylurea alone	799 (16%)	809 (17%)
Metformin+sulfonylurea	1196 (24%)	1207 (25%)
Other oral agent	10 (<1%)	9 (<1%)
Metformin and/or sulfonylurea+other oral agent	100 (2%)	93 (2%)
Insulin alone	286 (6%)	283 (6%)
Insulin+oral agent	402 (8%)	408 (8%)

Are the results of the trial valid ?

Aside from the allocated treatment, were groups treated equally (兩組其他治療條件一樣) ?

Answer: Yes

	Placebo group (n=4900)		Fenofibrate group (n=4895)	
	Change from baseline (%)	Number (%) at final visit*	Change from baseline (%)	Number (%) at final visit*
Cardiovascular medication				
Any antithrombotic	24·0	2744 (56%)	22·7	2688 (55%)
Aspirin	18·2	2348 (48%)	17·2	2291 (47%)
Other	9·2	622 (13%)	9·1	613 (13%)
Angiotensin-converting enzyme inhibitor	12·7	2348 (48%)	9·8	2197 (45%)
Angiotensin II receptor antagonist	14·8	991 (20%)	13·8	956 (20%)
β blocker	11·0	1290 (26%)	8·6	1179 (24%)
Calcium antagonist	7·1	1335 (27%)	5·4	1277 (26%)
Digoxin	5·6	201 (4%)	5·8	242 (5%)
Diuretic	7·7	1157 (24%)	5·0	1043 (21%)
Nitrate	5·6	577 (12%)	5·8	543 (11%)
Lipid-lowering agent†	36·0	1776 (36%)	19·0	944 (19%)
Blood-glucose-lowering medication				
Oral	9·9	3818 (78%)	9·7	3829 (78%)
Insulin	15·9	1464 (30%)	15·9	1467 (30%)

*Within 3 months of study close. †For this category only, defined as the cumulative number of patients who had used non-study lipid-lowering treatment for more than 3 months at any time. Significant differences at study close: angiotensin-converting enzyme inhibitors p=0·003, β blockers p=0·011, diuretics p=0·006, digoxin p=0·045, lipid-lowering agents p=<0·0001.

Table 4: **Patients on concominant medication between baseline and study close**

Are the results of the trial valid ?

Were all patients who entered the trial accounted for and were they analysed in the groups to which they were randomised

(所有進入試驗者皆列入統計，並依所分配的組別計算)？

Answer: Yes

adverse drug reactions, the respective frequencies of which were similar between groups. We continued to follow up patients who had discontinued therapy until death or study close; 22 patients were lost to follow-up and were assumed to be alive at the end of the study; a further 65 patients were not evaluable for morbidity at study close-out such that the primary outcome was confirmed in all but 87 participants (0·9%). There were 34 eligibility protocol violations, including 20 patients who were subsequently found not to fulfil WHO criteria for the diagnosis of diabetes. All these patients were included in the analysis.

Are the results of the trial valid ?

Were measures objective or were the patients and clinicians were blinded
(結果測量客觀，受試者及醫師都不知道所接受的治療為何)？

Answer: Yes

Methods

Patients

A detailed description of the design of the FIELD study—a double-blind, placebo-controlled trial done in 63 centres in Australia, New Zealand, and Finland—has been published.[18] In brief, patients with type 2 diabetes diagnosed according to WHO criteria[1] and aged 50–75 years were randomly allocated between February, 1998, and November, 2000, to once-daily micronised fenofibrate 200 mg (Laboratoires Fournier, Dijon, France) or matching placebo capsules. Patients were recruited from hospital clinics and community-based sources. All

What were the results ?

How large was the treatment effect (治療效果有多大) ?

Answer:

For entire cohort, the relative risk reduction(RRR) of 11% in total cardiovascular disease events corresponds to an absolute risk reduction(ARR) of 1.4% or the equivalent of needing to treat(NNT) around 70 patients for 5 years to prevent one or more cardiovascular disease events in one patient.

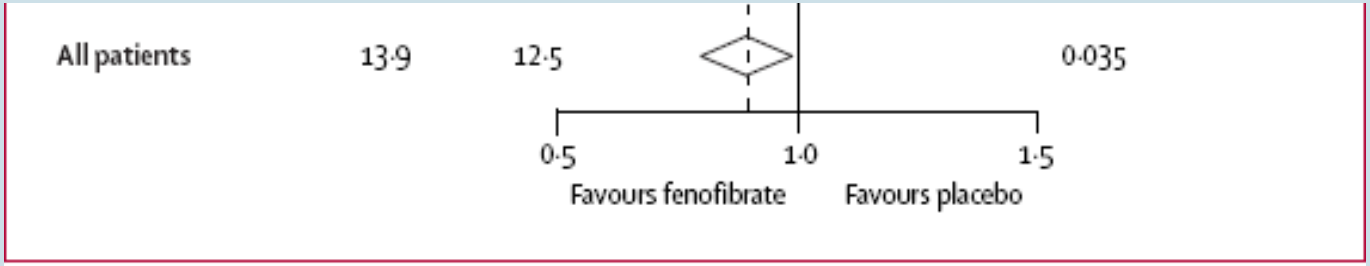


Figure 4: Effect of fenofibrate treatment on total cardiovascular disease (CVD) events (CVD death, myocardial infarction, stroke, coronary, or carotid revascularisation)

What were the results ?

How precise was the estimate of the treatment effect (治療效果的預測多準確) ?

Answer: Yes

	Placebo (n=4900)		Fenofibrate (n=4895)		HR (95% CI)	Log-rank p
	Number (%)*	Rate/1000 person-years at risk	Number (%)*	Rate/1000 person-years at risk		
Primary outcome						
Coronary events	288 (6%)	11·7	256 (5%)	10·4	0·89 (0·75–1·05)	0·16
Coronary heart disease mortality	93 (2%)	3·7	110 (2%)	4·4	1·19 (0·90–1·57)	0·22
Non-fatal myocardial infarction	207 (4%)	8·4	158 (3%)	6·4	0·76 (0·62–0·94)	0·010
Secondary outcome						
Total cardiovascular disease events	683 (14%)	29·0	612 (13%)	25·8	0·89 (0·80–0·99)	0·035
Cardiovascular disease mortality	127 (3%)	5·1	140 (3%)	5·6	1·11 (0·87–1·41)	0·41
Total mortality	323 (7%)	12·9	356 (7%)	14·2	1·11 (0·95–1·29)	0·18
Total stroke	175 (4%)	7·1	158 (3%)	6·4	0·90 (0·73–1·12)	0·36
Non-haemorrhagic stroke	158 (3%)	6·4	144 (3%)	5·8	0·91 (0·73–1·14)	0·43
Coronary revascularisation	364 (7%)	15·0	290 (6%)	11·9	0·79 (0·68–0·93)	0·003
All revascularisation†	471 (10%)	19·7	380 (8%)	15·8	0·80 (0·70–0·92)	0·001

*Only first event for each patient counted in each row. †Includes coronary, carotid, and all other peripheral revascularisation.

Table 3: **Effect of treatment on primary and secondary outcomes**[15]

Will the results help me in my patient care ?

Will the results help me in my patient care (適用於我的病人嗎) ?

Answer:

- Are the people in the study like my patient ? **younger**
- Did the study cover all aspects of problem ? **yes**
- Is the treatment feasible in my setting ? **yes**
- Will the potential benefits of treatment outweigh the potential harms of treatment for my patients ? **yes**
- Does it suggest a clear and useful plan of action ? **yes**

實證醫學結論

- Fenofibrate reduces total cardiovascular events, mainly due to fewer non-fatal myocardial infarctions and revascularisations.
- However, it did not significantly reduce the risk of the primary outcome of coronary events.
- The higher rate of starting statin therapy in patients allocated placebo might have masked a moderately larger treatment benefit.

	Treatment effect	Relative risk reduction (95% CI)*	p
Coronary heart disease event	Fenofibrate	19% (4–32)	0·01
	Statin use†	49% (36–59)	<0·001
Total cardiovascular disease	Fenofibrate	15% (5–24)	0·004
	Statin use†	26% (15–36)	<0·001

*Relative risk reduction=(1–HR)X100. †Use of non-study lipid-lowering therapy (predominantly statins) estimates risk of subsequent events (statin and selection effects into non-study lipid-lowering therapy) of those who have dropped in compared with those who have not at each event time during follow-up.

***Webtable 3*: Effects of allocation to fenofibrate adjusted for statin use in Cox regression analysis**

將EBM結果應用於病人身上

醫療現況	病人意願
由文獻結果得知臨床上可藉由Fibrates來降低DM病患發生心肌梗塞和需要血管重整的機率	Fibrates的服藥頻次為一天一次且產生副作用的機率低, 病患的接受度不錯
生活品質	**社會脈絡**
藉由Fibrates來降低DM病患(年輕且先前無心血管疾病)發生心肌梗塞和需要血管重整的機率以增進生活品質	Fenolip健保價7.5元(自費價25元), 服藥頻次一天一次, 對病患經濟影響小

Thank you for attentions ! ! !