ISRCTN64783481 https://doi.org/10.1186/ISRCTN64783481

Fenofibrate Intervention and Event Lowering in Diabetes

Submission date	Recruitment status	[_] Prospectively registered
27/09/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/10/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/03/2023	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctc.usyd.edu.au/trials/cardiovascular/field.htm

Contact information

Type(s)
Scientific

Contact name
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Contact details
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University of Sydney
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Australia
2040

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Fenofibrate Intervention and Event Lowering in Diabetes

Acronym
FIELD

Study objectives
The trial aims to determine whether treatment with fenofibrate, a potent modifier of blood lipid levels, will reduce the risk of fatal coronary heart disease in people with type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 10/09/2007: The study has been approved by local ethics committees at each participating institution.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
200 mg daily comicronized fenofibrate or matching placebo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fenofibrate

Primary outcome measure
First nonfatal myocardial infarction or coronary death

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1998

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Type 2 diabetes mellitus with onset after the age of 35 years
2. Men and women aged 50-75 years of age
3. Average total cholesterol 3.0-6.5 mmol/L
4. Triglycerides/high-density cholesterol ratio of 4.0 or higher, or triglycerides over 1.0 mmol/L

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
9,795

Total final enrolment
9795

Key exclusion criteria
Added 21/04/2008:
1. Triglyceride levels over 5.0 mmol/L
2. Participants could not be taking any lipid-modifying therapy at the start of the dietary run-in period. However, the protocol allows for statin or other lipid-lowering therapy to be added at any time after randomisation and recommends continuing study medication

Date of first enrolment
01/01/1998

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Australia

Finland

New Zealand

Study participating centre
NHMRC Clinical Trials Centre
Camperdown
Australia
2040

Sponsor information

Organisation
Australian National Health and Medical Research Council (NHMRC) Clinical Trials Centre

Sponsor details
Locked Bag 77
Camperdown NSW
Australia
1450

Sponsor type
Research council

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Industry

Funder Name
Fournier Pharma (France)

Funder Name
National Health and Medical Research Council (Australia)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2004		Yes	No
Results article	results	22/08/2005		Yes	No
Results article	results	26/11/2005		Yes	No
Results article	results	17/11/2007		Yes	No
Results article	results	08/01/2010		Yes	No
Results article	results	01/02/2011		Yes	No
Results article	results	01/02/2012		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	01/03/2015		Yes	No
Other publications	post-hoc analysis Post-hoc analysis	01/04/2018		Yes	No

Other publications	09/03/2023	10/03/2023	Yes	No