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

Fenofibrate Intervention and Event Lowering in Diabetes

Submission date	Recruitment status
27/09/2004	No longer recruiting
Registration date	**Overall study status**
19/10/2004	Completed
Last Edited	**Condition category**
10/03/2023	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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2040

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
First nonfatal myocardial infarction or coronary death

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

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)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
Protocol article	protocol	01/12/2004		Yes	No
Other publications	post-hoc analysis	01/04/2018		Yes	No
Other publications	Post-hoc analysis	09/03/2023	10/03/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes