

Fenofibrate Intervention and Event Lowering in Diabetes

Submission date 27/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/10/2004	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 10/03/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Australia
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes