

# Fenofibrate Intervention and Event Lowering in Diabetes

<b>Submission date</b> 27/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/10/2004	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 10/03/2023	<b>Condition category</b> 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

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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?
<a href="#">Protocol article</a>	protocol	01/12/2004		Yes	No
<a href="#">Results article</a>	results	22/08/2005		Yes	No
<a href="#">Results article</a>	results	26/11/2005		Yes	No
<a href="#">Results article</a>	results	17/11/2007		Yes	No
<a href="#">Results article</a>	results	08/01/2010		Yes	No
<a href="#">Results article</a>	results	01/02/2011		Yes	No
<a href="#">Results article</a>	results	01/02/2012		Yes	No
<a href="#">Results article</a>	results	01/03/2012		Yes	No
<a href="#">Results article</a>	results	01/03/2015		Yes	No
<a href="#">Other publications</a>	post-hoc analysis	01/04/2018		Yes	No
	Post-hoc analysis				

[Other publications](#)

09/03/2023

10/03/2023

Yes

No