# Atorvastatin in factorial with omega-3 fatty acid risk reduction in diabetes

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered	
04/08/2004		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
14/09/2004	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
22/08/2016	Nutritional, Metabolic, Endocrine		

### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Prof Rury R Holman

#### Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT)

NCT00141232

Protocol serial number

A2581114

# Study information

Scientific Title

#### Atorvastatin in Factorial with Omega-3 fatty acid Risk Reduction in Diabetes

#### Acronym

**AFORRD** 

#### **Study objectives**

Not provided at time of registration

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

## Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Type 2 diabetes

#### Interventions

Placebo-controlled double-blind,  $2 \times 2$  factorial randomisation - it is a one year treatment trial of 1000 participants, 250 randomised to each receive either:

- 1. Atorvastatin (Lipitor 20mg/day) and comparator (olive oil) (250 participants)
- 2. Omega-3 polyunsaturated fatty acids (PUFA) (Omacor 2g/day) and placebo (250 participants)
- 3. Atorvastatin and Omega-3 PUFA (250 participants)
- 4. Placebo and comparator (olive oil) (250 participants)

In addition, according to their cardiovascular disease (CVD) risk which is assessed at the start of the trial, all participants at greater than or equal to 20% 10-year CVD risk will be allocated (single blind) to the Atorvastatin treatment arm of the study at 16 weeks. If already in the treatment arm, their dose of Atorvastatin will be doubled.

#### Intervention Type

Mixed

#### Primary outcome(s)

Not provided at time of registration

#### Key secondary outcome(s))

Not provided at time of registration

## Completion date

31/07/2006

# **Eligibility**

## Key inclusion criteria

- 1. Aged 18 years or above
- 2. Have had Type 2 diabetes for at least 3 months
- 3. Not known to have had a cardiovascular event
- 4. Have provided written informed consent
- 5. In UK general practice

## Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

## Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/11/2004

#### Date of final enrolment

31/07/2006

# Locations

#### Countries of recruitment

United Kingdom

England

## Study participating centre Churchill Hospital

Oxford United Kingdom OX3 7LJ

# Sponsor information

#### Organisation

Pfizer Ltd

#### **ROR**

https://ror.org/04x4v8p40

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Pfizer UK

## Alternative Name(s)

Pfizer Ltd, Pfizer Limited

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

For-profit companies (industry)

#### Location

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2009	Yes	No
Results article	results	01/12/2010	Yes	No
Results article	results	01/10/2016	Yes	No