

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

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| Submission date 04/08/2004 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 14/09/2004 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 22/08/2016 | 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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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 x 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 |

