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

Submission date	Recruitment status	[X] Prospectively registered
04/08/2004	No longer recruiting	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00141232

Secondary identifying numbers
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

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 contact details to request a participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000 patients in 70 UK clinical centres

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
England

United Kingdom

Study participating centre
Churchill Hospital
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Pfizer Ltd

Sponsor details
IPC 2F, Walton Oaks
Dorking Road
Tadworth
United Kingdom
KT20 7NS

Sponsor type
Industry

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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