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HPS2-THRIVE: Treatment of High density lipoprotein to Reduce the Incidence of Vascular Events

Submission date	Recruitment status	[X] Prospectively registered
24/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/08/2022	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctsu.ox.ac.uk/~thrive/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2006-001885-17

IRAS number

ClinicalTrials.gov number
NCT00461630

Secondary identifying numbers
CTSUTHRIVE1

Study information

Scientific Title
HPS2-THRIVE: Treatment of High density lipoprotein to Reduce the Incidence of Vascular Events

Acronym
HPS2-THRIVE

Study objectives
Does niacin combined with Extended Release (ER) niacin/laropiprant 2 g daily prevent vascular events in high-risk patients who are receiving intensive Low Density Lipoprotein (LDL)-lowering treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (MREC), 04/08/2006, ref: 06/MRE12/43

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
http://www.ctsu.ox.ac.uk/~thrive/participants.htm

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
ER niacin/laropiprant 2 g daily versus matching placebo tablets. All patients receive LDL lowering therapy with either 40 mg of simvastatin or 10/40 mg ezetimibe/simvastatin.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ER niacin/laropiprant

Primary outcome measure
The effects of allocation to ER niacin/laropiprant 2 g versus placebo on major vascular events during the scheduled treatment period of at least four years.

Secondary outcome measures
The effects of allocation to ER niacin/laropiprant 2 g versus placebo during the scheduled treatment period on separate components of the primary endpoint:
1. Major coronary events
2. Total stroke
3. Revascularisation
4. Mortality, both overall and within particular categories of causes of death, and major vascular events in patients with coronary heart disease
5. Peripheral arterial disease
6. Cerebrovascular disease or diabetes mellitus

Overall study start date
01/08/2007

Completion date
01/01/2013

Eligibility

Key inclusion criteria
Sufferers of one of the following:
1. History of myocardial infarction
2. Cerebrovascular atherosclerotic disease (history of presumed ischaemic stroke, transient ischaemic attack or carotid revascularisation)
3. Peripheral arterial disease (i.e. intermittent claudication or history of revascularisation)
4. Diabetes mellitus with any of the above or with other evidence of symptomatic coronary heart disease (i.e. stable or unstable angina, or a history of coronary revascularisation or acute coronary syndrome)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25,673

Key exclusion criteria
1. Age less than 50 or more than 80 years at invitation to screening
2. Less than three months since presentation with acute myocardial infarction, coronary syndrome or stroke
3. Planned revascularisation procedure within three months after randomisation
4. Definite history of chronic liver disease, or abnormal liver function (i.e. Alanine Aminotransferase [ALT] more than 1.5 x Upper Limit of Normal [ULN])
5. Breathlessness at rest for any reason
6. Severe renal insufficiency (i.e. creatinine more than 200 µmol/L)
7. Evidence of active inflammatory muscle disease (e.g. dermatomyositis, polymyositis), or Creatine Kinase [CK] more than 3 x ULN
8. Previous significant adverse reaction to a statin, ezetimibe, niacin or ER niacin/laropiprant 2 g
9. Active peptic ulcer disease
10. Concurrent treatment with: fibric acid derivative ('fibrate'), niacin (nicotinic acid) at doses more than 100 mg daily, ezetimibe in combination with either simvastatin 80 mg or atorvastatin 20 - 80 mg or rosuvastatin 10 - 40 mg daily, or any potent CYP3A4 inhibitor

Date of first enrolment
01/08/2007

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
China

Denmark

England

Finland

Norway

Sweden

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Merck &Co., Inc (USA)

Alternative Name(s)
Merck & Co., Inc., Merck & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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?
Basic results				No	No
Results article	results	17/07/2014		Yes	No