

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

<b>Submission date</b> 24/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/08/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<http://www.ctsuo.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.ctsuo.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/laropirant

**Primary outcome measure**

The effects of allocation to ER niacin/laropirant 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/laropirant 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?
<a href="#">Basic results</a>				No	No
<a href="#">Results article</a>	results	17/07/2014		Yes	No