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Clinical effect and tolerability of atorvastatin versus placebo in patients with Pulmonary Arterial Hypertension: double-blinded, randomised, prospective phase III-b study for 12 weeks with adjusted doses of atorvastatin (40 - 80 mg daily)

Submission date 26/12/2006	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/01/2007	**Overall study status** Stopped	
Last Edited 15/04/2009	**Condition category** Circulatory System	

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

Secondary identifying numbers
STOP-PAH-001

Study information

Scientific Title

Acronym
STOP-PAH

Study objectives
Six minute walk distance will be significantly enhanced in the atorvastatin patient group compared to the placebo patient group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 15/04/2009: This trial was never initiated and therefore no ethics approval was sought.

Study design
Randomised, prospective, double-blind, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pulmonary hypertension

Interventions
The treatment will be 40, 80 mg atorvastatin orally versus placebo, three months of treatment per patient.

Intervention Type
Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)
Atorvastatin

Primary outcome measure
Six minute walk test after 12 weeks of treatment compared to baseline.

Secondary outcome measures
1. Short Form health survey (SF-36)
2. Borg scale
3. Modified NYHA class
4. Laboratory parameters
5. Adverse events
6. Concomitant medication

Overall study start date
01/04/2007

Completion date
01/04/2009

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Female and male patients of any racial origin with pulmonary arterial hypertension (PAH)
2. Having fulfilled his/her 18th birthday on day one of the study
3. Modified New York Heart Association (NYHA) functional class II and III
4. Unencouraged six minute walking distance at baseline less than 500 m
5. Symptomatic PAH due to idiopathic or familial PAH or associated with corrected congenital systemic-to-pulmonary shunts, drugs, toxins and collagen tissue disease (scleroderma, mixed collagenosis)
6. PAH diagnosed by right heart catheter showing:
6.1. Mean pulmonary arterial pressure (mPAP) more than 25 mmHg
6.2. Pulmonary capillary wedge pressure (PCWP) less than 15 mmHg
6.3. Pulmonary vascular resistance (PVR) at baseline of more than 320 dyne*sec/cm^5
7. Patient stable for at least eight weeks before enrolment
8. Able to understand and willing to sign the informed consent form
9. Negative pregnancy test at the start of the trial and highly effective contraception (oral or injectable contraceptives, intra-uterine device (IUD), sexual abstinence or vasectomised partner) throughout the study for women with child-bearing potential

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 patients

Key exclusion criteria
1. Pregnancy and/or lactation
2. Women of child-bearing potential not using appropriate contraceptive measures
3. PAH of any cause other than permitted in the entry criteria
4. Suspected pulmonary veno-occlusive disease based on pulmonary oedema during a previous vasoreactivity test or on abnormal findings compatible with that diagnosis (septal lines or pulmonary oedema at high resolution computer tomography)
5. Myopathy
6. Any change in disease-targeted therapy and calcium-channel-blockers within the last four weeks
7. Patients already taking a statin or fibrates
8. Any subject who had received any investigational medication within one month prior to the start of this study or who is scheduled to receive another investigational drug during the course of this study
9. Known hypersensitivity to hydroxymethylglutaryl-coenzyme A (HMG-CoA)-inhibitors (statins) or any of the excipients
10. Active liver disease or unexplained persistent elevations of serums transaminases, gamma-glutamyl transpeptidase (gGT), alkaline phosphatase (AP) more than three x upper limit of normal (ULN) and elevations of creatine kinase (CK) more than two x ULN
11. History or suspicion of inability to cooperate adequately
12. Systolic blood pressure less than 85 mmHg
13. Body weight less than 40 kg

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Austria

Germany

Netherlands

Switzerland

Study participating centre
Mittelweg 27
Frankfurt
Germany
60318

Sponsor information

Organisation
University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.klinikum.uni-heidelberg.de/

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Government

Funder Name
European Union (EU) - Project "Pulmotension": this is an investigator initiated trial

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