

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	☒ Prospectively registered ☐ Protocol
Registration date 26/01/2007	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 15/04/2009	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Short Form health survey (SF-36)
2. Borg scale
3. Modified NYHA class

4. Laboratory parameters
5. Adverse events
6. Concomitant medication

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/cm⁵
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration