

# 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)

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|--|---|--|
| <b>Submission date</b><br>26/12/2006   | <b>Recruitment status</b><br>Stopped            | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>26/01/2007 | <b>Overall study status</b><br>Stopped          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>15/04/2009       | <b>Condition category</b><br>Circulatory System | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

**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<sup>5</sup>
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  
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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