

# Clinical investigation into efficacy, haemodynamics and tolerability of simvastatin versus placebo in patients with pulmonary arterial hypertension

<b>Submission date</b> 13/05/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/02/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Hanna Mach

**Contact details**  
c/o Dr Riethmüller M/R/S  
Mittelweg 27  
Frankfurt  
Germany  
60318

## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00180713

**Clinical Trials Information System (CTIS)**  
2005-004863-41

**Protocol serial number**  
SIPHT-001; EudraCT number:

# Study information

## Scientific Title

## Acronym

SiPHT

## Study objectives

Simvastatin is significantly effective in lowering the mean pulmonary arterial pressure versus placebo after six months of therapy.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Justus-Liebig-Universität Giessen Ethikkomitee des FB Medizin on the 30th August 2006 (ref: 85/06).

## Study design

Double-blind, randomised, prospective, placebo-controlled (first phase, 6 months), open-label (second phase, 6 months) trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Pulmonary hypertension

## Interventions

Please note that as of 02/05/2008 the anticipated start date was updated. The previous anticipated start date was 01/08/2006.

## Interventions:

Effects of simvastatin or placebo on haemodynamics (cardiac catheterisation), electrocardiogram (ECG), echocardiogram, cardiac magnetic resonance, lung function test etc.

## Intervention Type

Drug

## Phase

Not Specified

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

Simvastatin

**Primary outcome(s)**

Pulmonary arterial pressure

**Key secondary outcome(s)**

1. Pulmonary vascular resistance
2. Cardiac output
3. Right ventricle mass
4. Six-minute walk test
5. Left ventricular (LV) systolic eccentricity index
6. Tei index
7. Right atrial area
8. Levels of brain natriuretic peptide (BNP) and inflammatory markers
9. Urinary iPF2alpha-III levels
10. Adverse events
11. Concomitant medication

**Completion date**

31/07/2008

**Eligibility****Key inclusion criteria**

1. Female and male patients of any racial origin with pulmonary hypertension (PH)
2. Having fulfilled his/her 18th birthday on day 1 of the study
3. Modified New York Heart Association (NYHA) class II or III
4. PH due to idiopathic pulmonary arterial hypertension or collagen vascular disease associated PH
5. Cardiac catheterisation within the last year consistent with PH, specifically pulmonary artery mean pressure (PAPM) greater than or equal to 25 mmHg (at rest), pulmonary capillary wedge pressure (PCWP) (or left ventricular [LV] end diastolic pressure) less than or equal to 15 mmHg, and peripheral vascular resistance (PVR) greater than 3 mmHg/l/min
6. Echocardiogram on day 1 consistent with PH, more specifically, evidence of right ventricular hypertrophy or dilation, evidence of normal left ventricular function, and absence of mitral valve stenosis
7. Six-minute walk test between 150 and 450 m
8. Patients receiving conventional PH therapy. Stable for one month.
9. Able to understand and willing to sign the informed consent form
10. Negative pregnancy test ( $\beta$ -human chorionic gonadotropin [HCG]) at the start of the trial and appropriate contraception throughout the study for women of 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. PH of any cause other than permitted in the entry criteria
3. Contraindication for cardiac magnetic resonance (CMR) scan or heart catheterisation
4. Any change in disease-targeted therapy within the last four weeks
5. Patients requiring prostanoid therapy at the start of the study
6. Patients already taking a statin
7. Any subject who has received any investigational medication within 1 month prior to the start of this study or who is scheduled to receive another investigational drug during the course of this study
8. Known intolerance to hydroxy-methylglutaryl coenzyme A (HMG-CoA)-inhibitors (statins) or any of the excipients
9. Active liver disease, porphyria or elevations of serums transaminases greater than three times upper limit of normal (ULN) or bilirubin greater than 1.5 x ULN
10. Concomitant administration of potent CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, human immunodeficiency virus [HIV] protease inhibitors, erythromycin, clarithromycin, telithromycin and nefazodone, ciclosporin and danazole)
11. History or suspicion of inability to cooperate adequately

**Date of first enrolment**

16/07/2007

**Date of final enrolment**

31/07/2008

**Locations**

**Countries of recruitment**

Germany

**Study participating centre**

c/o Dr Riethmüller M/R/S

Frankfurt

Germany

60318

**Sponsor information**

**Organisation**

University Hospital Giessen (Germany)

ROR

<https://ror.org/032nzv584>

## Funder(s)

### Funder type

University/education

### Funder Name

University Hospital Giessen (Germany)

## Results and Publications

### Individual participant data (IPD) sharing plan

### 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="#">Results article</a>	results	15/05/2010		Yes	No