

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

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

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Contact details

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Additional identifiers

EudraCT/CTIS number

2005-004863-41

IRAS number

ClinicalTrials.gov number

NCT00180713

Secondary identifying numbers

SIPHT-001; EudraCT number: 2005-004863-41

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 Ethikkommittee 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

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

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 measure

Pulmonary arterial pressure

Secondary outcome measures

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

Overall study start date

16/07/2007

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 (β -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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40 patients

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)

Sponsor details

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

University/education

Funder Name

University Hospital Giessen (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/05/2010		Yes	No