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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	[X] Prospectively registered [_] Protocol
Registration date 14/06/2006	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 02/02/2010	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

ClinicalTrials.gov (NCT)
NCT00180713

Protocol serial number
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

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 (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

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?
Results article	results	15/05/2010		Yes	No