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Dose-finding and safety of heparin aerosol application in idiopathic pulmonary fibrosis

Submission date 16/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/04/2006	**Overall study status** Completed	
Last Edited 03/05/2019	**Condition category** Respiratory	

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
DOSEFIB 18-NOV-05

Study information

Scientific Title
Dose-finding and safety of heparin aerosol application in idiopathic pulmonary fibrosis

Acronym
DOSEFIB

Study objectives
To identify suitable amounts of inhaled heparin that result in a prolonged alveolar anticoagulatory activity and to assess safety and tolerability of such heparin treatment in a period of 4 weeks

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Committee of the School of Medicine, Justus-Liebig-University Giessen, Germany on 21/02/2006, reference number: 11/06

Study design
Open label, single site

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Idiopathic Pulmonary Fibrosis

Interventions
Triple daily inhalation of 10,000 up to 24,000 units of unfractioned heparin

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Heparin

Primary outcome measure
Safety as based on the following five safety events:
1. Any otherwise unexplainable decline in forced vital capacity by more than 10%
2. Any otherwise unexplainable decline in diffusion capacity by more than 10%
3. Any otherwise unexplainable decline in 6 min walking distance by more than 20%
4. Any otherwise unexplainable decline in serum hemoglobin by more than 10%
5. Any occurrence of hemoptysis

Secondary outcome measures
1. Frequency of heparin induced antibodies
2. Recalcification times of bronchoalveolar lavage (BAL) fluids obtained at end of study
3. Change in capillary oxygen partial pressure
4. Change in oxygen saturation

Overall study start date
01/03/2006

Completion date
01/08/2006

Eligibility

Key inclusion criteria
1. Patients with idiopathic pulmonary fibrosis (IPF) according to consensus criteria
2. Age between 18 and 70
3. Completion of physical examination
4. Body weight of more than 40 kg
5. 40% < forced vital capacity (FVC) < 90%
6. 30% < diffusing capacity of the lung for carbon monoxide (Dlco) < 75%
7. Capillary pO2 >55 mmHg (with or without O2)
8. Signed informed consent
9. Requirements of Local Ethics Committee are met

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
19

Key exclusion criteria
1. Any hemoptysis of unknown reason
2. Any significant and otherwise unexplainable bleeding with reduction of hemoglobin values by more than 10% in patient's history
3. Pre-existing presence of heparin induced antibodies
4. Preceding surgery within last 6 weeks
5. Current gastric or duodenal ulcer or inflammatory bowel disease
6. Any oesophageal varicosis of any size
7. Current colon adenoma with previous gastrointestinal bleeding
8. Current lower respiratory tract infection with CRP >10 mg/l
9. Any suspected or proven active malignancy, especially lung cancer
10. Any need for systemic anticoagulation with International Normalized Ratio (INR) >1.5
11. Any treatment with another investigational drug
12. Acute or chronic left heart failure
13. Severe arterial hypertension (>200 mmHg systolic or >120 mmHg diastolic)
14. Inherited or acquired coagulation disorders resulting in prolonged bleeding time or an INR >1.5
15. Disseminated intravascular coagulation
16. Deficient thrombocyte function or platelet counts <40,000 /µl
17. Evidence for intracranial hemorrhage
18. Diabetic retinopathy
19. Severe hepatic insufficiency (bilirubin >10 mg%)
20. Renal insufficiency with creatinine values >3mg% or proteinuria >1 g per day
21. Primary or secondary immunodeficiency
22. Previous therapeutic radiation of the lungs or the mediastinum
23. Elevated intracranial pressure
24. Pregnancy, breast feading or lack of safe contraception
25. Patients whose underlying disease is not likely to permit them to survive the study - any hemoptysis of unknown reason
26. Sickle cell anemia

Date of first enrolment
01/03/2006

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
Germany

Study participating centre

Department of Internal Medicine
Giessen
Germany
35392

Sponsor information

Organisation
Individual Sponsor (Germany)

Sponsor details
c/o Werner Seeger
University of Giessen Lung Center
Director of the Department of Respiratory and Critical Care Medicine
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Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft) (DFG)

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	01/06/2010	03/05/2019	Yes	No