

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

Submission date 16/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/05/2019	Condition category Respiratory	<input type="checkbox"/> 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

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 unfractionated 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. $40\% < \text{forced vital capacity (FVC)} < 90\%$
6. $30\% < \text{diffusing capacity of the lung for carbon monoxide (Dlco)} < 75\%$
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 / μ l
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 feeding 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. Sick 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