

Extracellular proteasome in the alveolar space: characterisation and function under physiological and pathophysiological condition

Submission date 15/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/09/2017	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

Contact name
Dr Stephan Urs Sixt

Contact details
Klinik für Anesthesiologie und Intensivmedizin
Hufelandstrasse 55
Essen
Germany
45122

Additional identifiers

Study information

Scientific Title
Extracellular proteasome in the alveolar space: characterisation and function under physiological and pathophysiological condition: an observational study

Acronym
ALIHD

Study objectives

We hypothesised that 20S proteasome is present and functional in the extracellular alveolar space of healthy subjects and patients with Acute Respiratory Distress Syndrome (ARDS), sarcoidosis and in the alveolar space after lung transplantation in humans.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee (Vorsitzender der Ethikkommission, Institut für Pharmakologie, Universitätsklinikum Essen) on the 9th December 2002 (ref: 01-97-1697).

Study design

This study is an observational, single-centre study. The aim of this study is the description and characterisation of the extracellular alveolar proteasome in healthy and sick subjects.

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Extracellular proteasome in the alveolar space

Interventions

Healthy caucasians subjects and patients with ARDS, sarcoidosis and patients after lung transplantation were included after approval of the local ethics committee and informed written consent.

Observational trial:

Proteasomal activity will be measured in Broncho-Alveolar Lavage (BAL) supernatant from healthy subjects, patients with acute respiratory distress syndrome and lung transplantation using specific proteasomal fluorogenic substrates and I125 albumin, with and without specific proteasome inhibitors. After that the different enzyme activities of the study groups were compared with healthy subjects. Furthermore, gel filtration, western blot technique, Enzyme-Linked Immuno-Sorbent Assay (ELISA) and mass spectrometry, were applied for proteasome characterisation in the different study groups.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Enzyme activity using specific proteasomal fluorogenic substrates and I125 albumin, with and without specific proteasome inhibitors
2. Detection of 20S proteasome with polyclonal antibody (western-blot)
3. Detection of immunoproteasome with LMP2 and LMP7 antibody (western-blot)

4. Gel filtration to evaluate the molecular weight of the extracellular proteasome in the bronchoalveolar space
5. Mass spectrometry of the gel filtration revealed hydrolysing activity and ELISA technique for the amount of extracellular, alveolar proteasome

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Acute respiratory distress syndrome:
 - 1.1. Timing: acute onset
 - 1.2. Oxygenation: Partial Pressure of Oxygen in Arterial Blood (PaO₂)/Fraction of Inspired Oxygen (FiO₂) ratio less than 200 mmHg (regardless of Positive End Expiratory Pressure [PEEP])
 - 1.3. Chest radiograph: bilateral infiltrates seen on frontal chest radiograph
 - 1.4. Pulmonary Artery Wedge (PAW): less than 18 mmHg when measured or no clinical evidence of left atrial hypertension
2. Sarcoidosis
3. Lung transplantation: patient after lung transplantation were lavaged in a routine diagnostic, for the screening of organ rejection and infection
4. Aged 18 to 70 years, both genders

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Key exclusion criteria

1. Acute respiratory distress syndrome: contraindication against bronchoscopy
2. Sarcoidosis: contraindication against bronchoscopy
3. Lung transplantation: contraindication against bronchoscopy
4. Healthy subjects:
 - 4.1. Contraindication against bronchoscopy

- 4.2. Any lung diseases
- 4.3. Infection
- 4.4. Sepsis
- 4.5. Coronary heart disease

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Germany

Study participating centre

Klinik für Anesthesiologie und Intensivmedizin

Essen

Germany

45122

Sponsor information

Organisation

German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

ROR

<https://ror.org/018mejw64>

Funder(s)

Funder type

Research council

Funder Name

German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: PE 301/4-1)
- submitted

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	additional results	01/10/2014		Yes	No
Interim results article	initial findings	01/05/2007		Yes	No