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

Submission date 15/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2007	**Overall study status** Completed	
Last Edited 18/09/2017	**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
N/A

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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2003

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
300 subjects, including healthy subjects and patients with acute respiratory distress syndrome, sarcoidosis and lung transplantation.

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 fur Anasthesiologie und Intensivmedizin
Essen
Germany
45122

Sponsor information

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

Sponsor details
c/o Dr. Simone Mueller
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Sponsor type
Research council

Website
http://www.dfg.de/

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

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?

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