ISRCTN55161632 https://doi.org/10.1186/ISRCTN55161632

Detection of novel genetic variants within the aquaporins 1 and 5

Submission date	Recruitment status	[_] Prospectively registered
06/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/07/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2009	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Adamzik

Contact details
Klinik fur Anasthesiologie und Intensivmedizin
Hufelandstrasse 55
Essen
Germany
45122

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Detection of novel genetic polymorphisms (single nucleotide polymorphisms [SNPs]) within the aquaporins 1 and 5: an observational single-centre study

Study objectives
We hypothesised that single nucleotide polymorphisms (SNPs) within the aquaporins 1 and 5 contribute to the phenotypic variability of acute respiratory distress syndrome (ARDS), sepsis or bronchial asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Vorsitzender der Ethikkommission, Institut für Pharmakologie, Universitätsklinikum Essen) approved on the 9th December 2002 (ref: 01-97-1697, 05-2776, 06-3078, 07-3313)

Study design
Observational single-centre case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Aquaporines, cell migration and inflammation

Interventions
The following analyses will be performed on each participant:
1. Deoxyribonucleic acid (DNA) extraction from rest material of the routine diagnostic, e.g., saliva, urine or blood
2. Identification of novel DNA polymorphisms through sequencing polymerase chain reaction (PCR) products of the AQP1 and 5 promoter. The method of "slowdown PCR" should be used to amplify promoter fragments with extremely high GC content (greater than 85%).
3. Determination of transcriptional activity of haplotypes by reporter assays in different cell lines
4. Haplotype-dependent analysis of radiation and chemotherapeutics on cell proliferation in cell systems
5. Haplotype-dependent analysis of messenger ribonucleic acid (mRNA) level by quantitative real time PCR
6. Haplotype-dependent analysis of protein level by Western Blot
7. Haplotype-dependent analysis of cell migration
8. Haplotype-dependent analysis of transcription factors which bind to the polymorphic regions

by electrophoretic mobility shift assay (EMSA)
9. Genotyping of ARDS, sepsis, bronchial asthma patients and healthy caucasian subjects by restriction fragment length polymorphism (RFLP) and pyrosequencing and haplotype-dependent analysis of survival and disease course using SPSS and GraphPad Prism software

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Detection of SNPs wthin the Aqquaporin 1 and 5 gen which contribute to the phenotypic variability of ARDS, sepsis and bronchial asthma, measured at 30 day survival and 100 day survival

Secondary outcome measures
Analysis of survival, disease course and rehabilitation, measured at 30 day survival and 100 day survival

Overall study start date
01/01/2005

Completion date
01/01/2011

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. Lung function testing with body plethysmography-revealed bronchial asthma
3. Patients with severe sepsis
4. Aged 18 to 70 years, both genders

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200 healthy caucasian subjects, 150 ARDS-, 200 sepsis- and 100 bronchial asthma patients

Key exclusion criteria
No written informed consent is obtained

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2011

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
Lebenswissenschaften 1
Geschaftsstelle
Kennedyallee 40
Bonn
Germany
53170

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) - pending as of 06/05/2009

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	01/11/2008		Yes	No