

Detection of novel genetic variants within the aquaporins 1 and 5

Submission date 06/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/07/2009	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

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

Study type(s)

Diagnostic

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(s)

Detection of SNPs within the Aquaporin 1 and 5 gene which contribute to the phenotypic variability of ARDS, sepsis and bronchial asthma, measured at 30 day survival and 100 day survival

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 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) - pending as of 06/05/2009

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	results	01/11/2008		Yes	No