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Sequential maintenance immunosuppression with mycophenolate and prednisolone: a randomised interventional trial in progressive immunoglobulin A nephritis (IgAN)

Submission date 27/04/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/05/2008	**Overall study status** Completed	
Last Edited 12/05/2008	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-000443-99

Protocol serial number
EudraCT-Nr:

Study information

Scientific Title

Acronym
MIgAN

Study objectives
With our investigator-initiated MIgAN study, we should like to test two hypotheses:
1. Further loss of renal function will occur in cases with progressive type two immunoglobulin A nephritis (IgAN) even after immunosuppressive induction therapy and while on angiotensin converting enzyme (ACE) inhibitor therapy
2. Sequential maintenance immunosuppression with mycophenolate and low dose prednisolone is able to prevent this loss better than ACE inhibition alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the University of Ulm Ethics Committee on the 9th April 2008 (ref: 13/08).

Primary study design
Interventional

Study design
Investigator-initiated randomised controlled unblinded interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mesangioproliferative IgA glomerulonephritis

Interventions
After enrolment phase, two patient groups are randomly assigned:
1. The mycophenolate group is treated with daily 2 x 360 mg oral mycophenolate combined with 2 x 2.5 mg oral prednisolone and the supportive standard therapy
2. The control group is treated with the supportive standard therapy alone consisting with an angiotensin-converting-enzyme inhibitor (ACEi) and/or an angiotensin receptor blocker (ARB)

The maximum duration of treatment is 36 months and the total duration of follow-up of all arms is 36 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mycophenolate, prednisolone

Primary outcome(s)
The frequency of a GFR loss greater than 20% in the mycophenolate group and in controls. The loss is estimated by the difference from the best GFR after induction therapy. The primary end-point will be measured at the end of month 36.

Key secondary outcome(s)
1. Urinary protein/creatinine ratio
2. Need for any further temporary or permanent medication (antihypertensives, antidiabetics, antiinfectives, etc.)
3. Hospitalisation
4. Dialysis
5. Death

All secondary end-points will be measured every three months in each patient.

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Mesangioproliferative IgA glomerulonephritis in kidney biopsy
2. Steadily progressive type IgAN = loss of renal function of 2 to 3 ml/min per month before immunosuppressive induction therapy
3. Completion of any form of an immunosuppressive induction protocol (Pozzi, Ballardie, Rasche, experimental)
4. Still impaired renal function after induction therapy with a glomerular filtration rate (GFR) less than 60 ml/min
5. Aged between 18 and 68 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Secondary forms of IgAN e.g. anti-nuclear antibody positive (ANA+) lupus, anti-neutrophil cytoplasmic antibody positive (ANCA+) vasculitis, human immunodeficiency virus (HIV), liver cirrhosis
2. Rapidly progressive type three IgAN with crescents in greater than or equal to 30% of glomeruli
3. Serum creatinine less than 130 mcmol/l or greater than 400 mcmol/l after induction therapy

Date of first enrolment
01/07/2008

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Germany

Study participating centre
Sektion Nephrologie
Ulm
Germany
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Sponsor information

Organisation
Universitätsklinikum Ulm (Germany)

ROR
https://ror.org/05emabm63

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration