

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 12/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/05/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

MlgAN

Study objectives

With our investigator-initiated MlgAN 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).

Study design

Investigator-initiated randomised controlled unblinded interventional study

Primary study design

Interventional

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

D-89081

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