Second Dutch Lupus Nephritis trial

Submission date	Recruitment status	Prospectively registered
27/01/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
27/01/2006	Completed	Results
Last Edited	Condition category	Individual participant data
13/11/2008	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number NTR452

Study information

Scientific Title

Comparison of short course cyclophosphamide followed by mycophenolate mofetil versus long course cyclophosphamide in the treatment of proliferative lupus nephritis

Study objectives

Short course cyclophosphamide followed by mycophenolate mofetil will reduce renal relapses to 33% (versus 10% in patients treated with long-course cyclophosphamide)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Proliferative lupus nephritis

Interventions

Patients will be randomised between long-cyclophosphamide (six monthly courses, 750 mg/m^2) followed by either six 3-monthly courses cyclophosphamide or mycophelolate mofetil, both regimes in combination with prednisone. After 2 years all patients will continue for another 2 years with maintenance therapy, consisting of azathioprine 2 mg/kg.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cyclophosphamide, mycophenolate mofetil

Primary outcome(s)

Number of renal relapses

Key secondary outcome(s))

- 1. Longitudinal follow-up of creatinine, proteinuria, sediment, complement levels, anti-double stranded deoxyribonucleic acid (anti-dsDNA), Systemic Lupus Erythematosus Disease Activity Index (SLEDAI), Systemic Lupus International Collaborating Clinics (SLICC), Dutch lupus nephritis questionnaire, 36-item short form health survey (SF-36), renal histology, IF-skin
- 2. Extra-renal exacerbations of SLE
- 3. Pregnancy
- 4. Death

Completion date

01/01/2008

Eligibility

Key inclusion criteria

- 1. Aged 18 70 years
- 2. Systemic lupus erythematosus (SLE) (presence of at least 4 American College of Rheumatology [ACR]-criteria for SLE)
- 3. Proliferative lupus nephritis:
- 3.1. Biopsy proven lupus nephritis World Health Organization (WHO) class III or IV (according to Churg 1995)
- 3.2. 'Active sediment': greater than 5 erythrocytes per high powered field (HPF) and/or cel cylinders
- 3.3. Proteinuria greater than 0.5 g/day
- 4. Adequate contraception
- 5. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Active infection
- 2. Pregnancy
- 3. Known allergy for one of the study drugs
- 4. Malignancy less than 5 years prior to inclusion

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Groningen

Groningen Netherlands 9700 RB

Sponsor information

Organisation

Sponsor not yet defined (The Netherlands)

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Kidney Foundation (Nierstichting Nederland) (The Netherlands)

Alternative Name(s)

Dutch Kidney Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration