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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
Dr Marc Bijl

Contact details
University Medical Centre Groningen
Department of Clinical Immunology
P.O. Box 30.001
Groningen
Netherlands
9700 RB
+31 (0)50 3612945
m.bijl@int.umcg.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure

Number of renal relapses

Secondary outcome measures
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

Overall study start date
01/01/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
124

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)

Sponsor details
-
-
Netherlands
-

Sponsor type
Not defined

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

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