

# Second Dutch Lupus Nephritis trial

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/11/2008	<b>Condition category</b> Musculoskeletal 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

**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

### **Primary study design**

Interventional

### **Study design**

Multicentre, randomised controlled trial

### **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<sup>2</sup>) followed by either six 3-monthly courses cyclophosphamide or mycophenolate 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