ISRCTN34265870 https://doi.org/10.1186/ISRCTN34265870

A randomized trial comparing cyclosporine versus azathioprine for maintenance therapy in diffuse lupus nephritis

Submission date 07/07/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/11/2004	**Overall study status** Completed	
Last Edited 11/02/2008	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Claudio Ponticelli

Contact details
via Ampere 126
Milano
Italy
20131

Additional identifiers

Protocol serial number
NEO-I-22

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Lupus nephritis

Interventions
Administration of 3 intravenous methylprednisolone pulses followed by a 2-3 month treatment with prednisone and oral cyclophosphamide. Patients with serum creatinine ≤1.5 mg/dl, proteinuria ≥0.5 g per day and diastolic blood pressure <90 mmHg were then randomized to receive cyclosporine or azathioprine for two years.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2004

Eligibility

Key inclusion criteria
Seventy five patients presenting with diffuse proliferative lupus nephritis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Italy

Study participating centre
via Ampere 126
Milano
Italy
20131

Sponsor information

Organisation
Novartis Farma (Italy)

ROR
https://ror.org/04rcxhq50

Funder(s)

Funder type
Industry

Funder Name
The study was sponsored by Novartis and monitored by an external society. The steering committee approved the study protocol, case report forms, statistical analysis plan, progress of

the study and analysis, as well as the reporting of the data, whatever the outcome of the study. The sponsors could comment on the manuscript before submission, but the final version was the sole responsibility of the authors. In addition, the steering committee had full access to the data files of the study.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2006		Yes	No