

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

Registration date
22/11/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
11/02/2008

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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