

Enteric coat mycophenolate sodium versus intravenous cyclophosphamide for severe paediatric lupus nephritis

Submission date 07/07/2009	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 29/07/2009	Overall study status Completed	☐ Protocol
Last Edited 29/07/2009	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Study information

Scientific Title
Enteric coat mycophenolate sodium versus intravenous cyclophosphamide for severe paediatric lupus nephritis: a multicentre randomised controlled trial

Study objectives

Is oral enteric coated mycophenolate sodium better than intravenous (IV) cyclophosphamide in paediatric lupus nephritis?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Joint Research Ethics Committee, Bangkok, Thailand, approved on the 17th June 2009 (ref: JREC008/2009)

Primary study design

Interventional

Study design

Multicentre open-label randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Paediatric lupus nephritis

Interventions

Intervention arm:

Enteric coated mycophenolate sodium (myfortic®) 720 - 860 mg/m²/day via oral administration twice daily + oral steroid.

Total duration of treatment: 12 months

Total duration of follow-up: 12 months

Control arm:

Cyclophosphamide 750 - 1000 mg/m²/day (maximum dose 1000 mg/day) via intravenous drip monthly for 6 months then every 3 months + oral steroid.

Total duration of treatment: 12 months

Total duration of follow-up: 12 months

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Mycophenolate sodium, cyclophosphamide

Primary outcome(s)

1. Complete and/or partial remission at the end of month 6
2. Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) score at the end of month 6

Key secondary outcome(s)

1. Rate of end-stage renal disease (ESRD) or chronic renal failure (CRF) at month 12
2. Death rate
3. Infection rate
4. Gastrointestinal (GI) side-effect rate
5. Rate of relapse
6. Rate of renal relapse
7. Dosage of concomitant steroid

Completion date

30/06/2012

Eligibility

Key inclusion criteria

1. 7 - 15 year old children (either sex) who had lupus according to American Rheumatology Association criteria (first the diagnosis time was between 7 - 15 years old)
2. Renal histology revealed lupus nephritis class III or IV according to World Health Organization (WHO) classification:
 - 2.1. Lupus nephritis class III include one of these following:
 - 2.1.1. Nephritic range proteinuria - urine protein/creatinine ratio equal or more than 2
 - 2.1.2. Acute nephritis - oedema, hypertension and haematuria
 - 2.1.3. Renal insufficiency - estimated glomerular filtration rate (eGFR) less than 90
 - 2.2. Lupus nephritis class IV
3. Serum creatinine not more than 3 mg/dl
4. Must stop oral cyclophosphamide for at least 6 month before enter to the trial
5. Parents and child was informed and give the consent to participate the trial

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 Years

Upper age limit

15 Years

Sex

All

Key exclusion criteria

1. Renal histopathology showed crescent more than 50% of total glomeruli
2. Previously received immunoglobulins
3. Previously undertaken plasmapheresis

4. Previously received mycophenolate
5. Previously received intravenous cyclophosphamide
6. Unable to swallow the tablets
7. Known to have serious illness, i.e., cancer, serious infection before entry to the trial

Date of first enrolment

15/07/2009

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

Thailand

Study participating centre

Department of Pediatrics

Chiang Mai

Thailand

50200

Sponsor information

Organisation

Thailand Clinical Research Collaboration Network (CRCN)

Funder(s)

Funder type

Research council

Funder Name

Thailand Clinical Research Collaboration Network (CRCN) and Office of National Research Council of Thailand (Thailand) (ref: CRCN -2552-๕03)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration