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

Submission date
07/07/2009

Registration date
29/07/2009

Last Edited
29/07/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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)

Study design
Multicentre open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (Thai only)

Health condition(s) or problem(s) studied
Paediatric lupus nephritis

Interventions
Intervention arm:
Enteric coated mycophenolate sodium (myfortic®) 720 - 860 mg/m^2/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/m^2/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 measure
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

Secondary outcome measures
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

Overall study start date
15/07/2009

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

Age group
Child

Lower age limit
7 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Renal histopathology showed crescent more than 50% of total glomeruli
2. Previously received immunoglobulins
3. Previously undertaken plasmapheresis
4. Peviously 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)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.crcn.in.th

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-¢03)

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