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A randomised, placebo controlled trial of prednisone in early Henoch Schonlein Purpura

Submission date 08/03/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/03/2004	**Overall study status** Completed	
Last Edited 24/08/2007	**Condition category** Haematological Disorders	

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
95/25S(E)

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Henoch Schonlein Purpura

Interventions
Intervention:
Prednisone 2 mg/kg for 7 days, 75% on days 8 and 9, 50% on days 10 and 11 and 25% on days 12, 13, 14, then stopped.

Control:
Comparison group was an identical appearing placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prednisone

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1996

Completion date
31/01/2000

Eligibility

Key inclusion criteria
Eligible participants were children between the ages of 2 and 15, presenting to the emergency room within 7 days of onset of Henoch Schonlein Purpura.

Children were excluded if:
1. Another explanation for purpura was present
2. They had a known underlying systemic vasculitis
3. They had been treated with any form of corticosteroids in the preceding month
4. They had a known chronic illness affecting the renal, gastrointestinal or immune systems
5. They had an active infection
6. They were experiencing a life-threatening complication of Henoch Schonlein Purpura

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/1996

Date of final enrolment
31/01/2000

Locations

Countries of recruitment
Canada

Study participating centre
IWK Health Centre
Halifax
Canada
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Sponsor information

Organisation
Children's Hospital of Eastern Ontario Research Institute (CHEORI) (Canada)

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Sponsor type
Research organisation

ROR
https://ror.org/05nsbhw27

Funder(s)

Funder type
Research organisation

Funder Name
Children's Hospital of Eastern Ontario Research Institute (CHEORI) (Canada) (ref: 95/25S[E])

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	02/04/2004		Yes	No