LCH-II Langerhans cell histiocytosis: treatment protocol of the second international study

Submission date Recruitment status [X] Prospectively registered 01/07/2001 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 01/07/2001 Completed [X] Results [] Individual participant data **Last Edited** Condition category 02/09/2008 Haematological Disorders

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr--

Contact details

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Additional identifiers

Protocol serial number LCH 9605

Study information

Scientific Title

Study objectives

To compare intensification of treatment with an improved outcome.

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)

Treatment

Health condition(s) or problem(s) studied

Langerhans cell histiocytosis

Interventions

Risk group patients are randomised to either:

- 1. Arm A: Initial treatment with oral prednisone and vinblastine. Continuation treatment with oral 6-mercaptopurine plus pulses of oral prednisone and vinblastine.
- 2. Arm B: Initial treatment with oral prednisone and vinblastine. Continuation treatment with oral 6-mercaptopurine plus pulses of oral prednisone and vinblastine followed by etoposide.

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

31/12/2007

Eligibility

Key inclusion criteria

- 1. Definitive diagnosis of Langerhans cell histiocytosis
- 2. Aged under 18 years with involvement of haematopetic system, liver, lungs or spleen or aged under 2 years
- 3. No prior treatment for Langerhans cell histiocytosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 years

Sex

All

Key exclusion criteria

Does not comply with above criteria

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

United Kingdom

England

Austria

Study participating centre UKCCCR Register Co-ordinator

London United Kingdom NW1 2DA

Sponsor information

Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

ROR

https://ror.org/054225q67

Funder(s)

Funder type

Research organisation

Funder Name

Children's Cancer Research Institute (Austria)

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	01/03/2008		Yes	No