

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

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

Primary study design

Interventional

Study design

Randomised controlled trial

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