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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
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

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

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
193

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
Austria

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
222 Euston Road
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United Kingdom
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Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Research organisation

Funder Name
Children's Cancer Research Institute (Austria)

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	01/03/2008		Yes	No