Treatment Protocol of the First International Study of Langerhans Cell Histiocytosis in adults

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To define and implement an uniform initial evaluation and stratification on adult patients with LCH, to uniform the treatment of adult patients with LCH and to improve treatment results with respect to survival, therapy response, prevention of...

Ethical review	Approved WMO
Status	Pending
Health condition type	White blood cell disorders
Study type	Interventional

Summary

ID

NL-OMON30781

Source
ToetsingOnline

Brief title
Treatment of LCH in adults

Condition

- White blood cell disorders
- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
Langerhans Cell Histiocytosis; LCH

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adults, LCH, Treatment

Outcome measures

Primary outcome

definition and implementation of an uniform treatment for patients with single system LCH, multisystem LCH and pulmonary isolated LCH, implementation of uniform initial evaluation and stratification criteria.

Secondary outcome

Not applicable.

Study description

Background summary

Langerhans Cell Histiocytosis is a rare, tumor-like disease characterized by the dysregulated growth, activity and trafficking of Langerhans cells. It has an unpredictable course and can be fatal. The cause of the disease is unknown. The disease has been better recognized in children and thus most of the available information concerning clinical features, pathogenesis and treatment derives from the pediatric experience.
Limited experience is avalaible so far on LCH in adult patients.

Study objective

To define and implement an uniform initial evaluation and stratification on adult patients with LCH, to uniform the treatment of adult patients with LCH and to improve treatment results with respect to survival, therapy response, prevention of disease recurrence and late effects.

Study design

The study is an intervention study and for patients in group 2, the duration of treatment will be the object of a randomized study, 6 months versus 12 months.

Intervention

Group 1: treatment with Prednisone, Vinblastine and Mercaptopurine.
Prednisone is given orally as tablets, daily during the initial 6 weeks, then as 5 daily pulses every 3 weeks during the continuation treatment.
Mecaptopurine is given as daily oral tablets during the continuation therapy.
Vinblastine is given intravenously as an injection weekly the initial 6 weeks, and every 3 weeks during the continuation treatment.
Total duration of treatment is 6 months.

Group 2: same as group 1.
Total of duration of treatment will be the object of a randomized study: 6 months versus 12 months

Group 3: an observational phase of 6 months after cigarette smoke withdrawal. In case of progression of the symptoms or pulmonary dysfunction, treatment phase starts: steroid monotherapy with Prednisone for 6 months.

Study burden and risks

The treatment requires frequent visits to the hospital for administration of the chemotherapy as well as monitoring for potential complications as is normally required for all other regular/standard systemic treatment.
Side effects of the treatment with Prednisone, and/or Vinblastine and Mercaptopurine are already known, but will appear.

Benefit to be gained from participation in this research study is control of the disease. Information will be gained that will be useful to researchers studying the disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- definitive diagnosis of LCH
- no prior cytoreductive treatment for LCH

Exclusion criteria

- patients with severe impairment of clinical condition including severely impaired pulmonary function, long term oxygen therapy or cor pulmonale.
- treatment with immune suppressive agents and/or biphosphonates within 4 weeks from baseline evaluation
- pregnancy

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Blastivin
Generic name:	Vinblastine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Prednison
Generic name:	Prednison
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Puri-Nethol
Generic name:	Mercaptopurine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	08-08-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-002392-40-NL
CCMO	NL13165.029.07