Treatment protocol of the first international study for Langerhans Cell Histiocytosis in Adults

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24739

Source
Nationaal Trial Register

Brief title
LCH-A1

Health condition

Langerhans Cell Histiocytosis; Langerhans Cel Histiocytose

Sponsors and support

Primary sponsor: VU University Medical Center Amsterdam,
Department of Hematology
Source(s) of monetary or material Support: VU University Medical Center Amsterdam,
department of Hematology

Intervention

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

- to explore the therapeutic efficacy on adult patients of the standard regimen for multisystem LCH in children, i.e. the combination of vinblastine and prednisone. Endpoints will be survival, reactivation-free survival, permanent sequelae.

- to examine if an extended continuation therapy may reduce disease reactivations occuring after treatment completion in patients with multisystem LCH.

- to describe the natural history of isolated pulmonary disease and in particular the role of smoking cessation on the disease course.

- to explore the therapeutic efficacy of steroid monotherapy in adult patients with isolated pulmonary disease showing disease progression.

Study description

Background summary

LCH-A1 study is an international multicenter study for Langerhans Cell Histiocytosis.
This is a rare, tumor-like disease thas has an unpredicatable course and can be fatal. The cause of this disease is unknown.
The targeted number of participants is 1200 patients; for the Netherlands the targeted number is 20 patients.
The study is designed for 3 groups of patients.
Patient population in group 1 are patients with single system multifocal bone lesions or localized special site involvement.
Group 2 consists of patients with multisystem disease and group 3 consists of patients with isolated pulmonary disease.
Treatment for group 1 is 6 months of treatment with Prednisone, Vinblastine and Mercaptopurine.
Treatment for group 2 is the same as in group 1. Patients are randomized for 6 months treatment versus 12 months.
Treatment in group 3 is an observation phase for 6 months after smoking cessation. In case of progression of the symptoms or pulmonary dysfunction 6 months steroid monotherapy is given.
Duration of treatment is for all patients 6 months till 12 months and a follow up period of 6 years.

Study objective

Improvement of standardization in diagnosis and treatment of adult LCH

Study design

pre-treatment, at week 6 and every 3 months during treatment (i.e. month 3, month 6 and 9 when appropriate) and then at treatment completion.
thereafter every 6 months for the first 3 years. and once a year during the following 3 years.

Intervention

- Patients in group 1 (single system disease at risk): treatment with Prednisone, Vinblastine and Mercaptopurine.

Initial treatment: Prednisone 1 mg/kg/day (not to exceed 60 mg) as a 4-week course, tapering over a period of 2 weeks.
Vinblastine 6 mg/m2 iv bolus (not to exceed 10 mg), day 1,8,15,22,29,36.

Continuation treatment: starting at day 43 after initial treatment. Mercaptopurine: 30 mg/m2(not to exceed 50 mg) daily until completion of treatment. Prednisone: 1 mg/kg/day (not to exceed 60 mg) day 1-5 every 3 weeks until completion of treatment.
Vinblastine: 6 mg/m2 iv bolus (not to exceed10 mg) day 1 every 3 weeks until completion of treatment. (starting 3 weeks after the last vinblastine injection of the initial treatment.

total duration of treatment is 6 months.

- Patients in group 2, multisystem LCH:treatment with Prednisone, Vinblastine and Mercaptopurine for 6 months versus treatment with Prednisone, Vinblastine and Mercaptopurine for 12 months.
Intervention for group 2 is the same as for group 1; total duration of treatment will be the object of randomization: 6 months vs 12 months.

- Patients in group 3 (isolated pulmonary disease): an observational period of 6 months afer cigarette smoke withdrawal. In case of progression of the symptoms of pulmonary dysfunction, treatment phase will be started with Prednisone monotherapy for 6 monthsat the following dosage:

- 1mg/kg/day (not to exceed 60 mg), daily for 1 month.

- 0.5 mg/kg/day, daily for 1 month.

- 0.25 mg/kg/day daily for 2 months.

- 0.125 mg/kg/day daily for 2 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. definitive diagnosis of LCH

2. no prior cytoreductive treatment for LCH

3. age 18-50 years for group 1 and 2

4. age 18-75 years for group 3

Exclusion criteria

1. patients with severe impairment of clinical condition including severely impaired pulmonary function, long term oxygen therapy or cor pulmonale.

2. treatment with immune suppressive agents and/or bisphosphonates within 4 weeks from baseline evaluation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2007
Enrollment:	1200
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-03-2008
Application type:	First submission

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
NTR-new	NL1171
NTR-old	NTR1216
Other	MEC VU University Medical Center Amsterdam : 2007/169
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A