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

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Improvement of standardization in diagnosis and treatment of adult LCH

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24739

Bron
NTR

Verkorte titel
LCH-A1

Aandoening

Langerhans Cell Histiocytosis; Langerhans Cel Histiocytose

Ondersteuning

Primaire sponsor: VU University Medical Center Amsterdam, Department of Hematology
Overige ondersteuning: VU University Medical Center Amsterdam, department of Hematology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Improvement of standardization in diagnosis and treatment of adult LCH

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

- 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-10-2007
Aantal proefpersonen:	1200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A