PHASE II STUDY FOR THE TREATMENT OF CHRONIC GRAFT-VERSUS-HOST DISEASE OF THE LIVER OR LUNGS WITH ADJUNCT EXTRACORPOREAL PHOTOIMMUNOTHERAPY

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to evaluate the safety and efficacy of ECP as adjunct first-line therapy in patients with newly diagnosed chronic GVHD of the liver or lungs

Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON31393

Source
ToetsingOnline

Brief title
nvt

Condition

- Autoimmune disorders

Synonym
chronic graft-versus-host disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Therakos,Therakos Inc. doneert de ECP machine en de benodigde kits

Intervention

Keyword: cGVHD, extracorporal photopheresis, Graft versus Host disease, methoxsalen

Outcome measures

Primary outcome

GVHD response of the liver or lungs defined as response of liver or lung

manifestations to first-line immunosuppressive treatment

Secondary outcome

Transplant-related mortality

Relapse-free survival

Overall survival

Time to complete resolution of chronic GVHD to first-line immunosuppressive

therapy

Time to discontinuation of immunosuppressive treatment

Duration of response to first-line immunosuppressive therapy

Percent of patients in need of secondary treatment for chronic GVHD

Response to secondary treatment for chronic GVHD

Incidence of bacterial infections

Incidence of viral infections

Incidence of fungal infections

Side effects of ECP

Study description

Background summary

Chronic GVHD is the major cause of nonrelapse mortality in patients surviving more than 2 years after allogeneic HSCT, and increasing severity of chronic GVHD is associated with higher nonrelapse mortality rates. Infection from a broad array of pathogens is the major cause of death, followed by progressive organ failure from chronic GVHD involvement and/or GVHD treatment. During the past 30 years survival of patients with chronic GVHD has not improved. Thus, new therapeutic approaches to improve treatment response of patients with chronic GVHD are urgently needed.

Study objective

to evaluate the safety and efficacy of ECP as adjunct first-line therapy in patients with newly diagnosed chronic GVHD of the liver or lungs

Study design

This is a phase II study to evaluate the safety and efficacy of ECP as adjunct first-line therapy in patients with newly diagnosed chronic GVHD of the liver or lungs. Patients must be in need of systemic immunosuppressive therapy defined as chronic GVHD involving three or more organs or with a score of 2 or greater in any single organ

Intervention

extracorporeal photopheresis

Study burden and risks

ECP may cause hypotension and allergic reactions

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

Presence of at least one diagnostic clinical sign of chronic GVHD or an appropriate constellation of distinctive signs confirmed by biopsy or other relevant diagnostic tests;Presence of liver manifestation of chronic GVHD after allogeneic HSCT;Presence of lung manifestation of chronic GVHD after allogeneic HSCT (bronchiolitis obliterans either confirmed by lung biopsy or diagnosed via pulmonary function and radiology testing);Indication for systemic immunosuppressive therapy defined as chronic GVHD that involves three or more organs or with a score of 2 or greater in any single organ.

Exclusion criteria

Patients with acute GVHD;Hypersensitivity or allergy to 8-methoxypsoralen;Hypersensitivity or allergy to both heparin and citrate products;Use of immunosuppressive medication other than CSA, FK506 and corticosteroids

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	extracorporeal photopheresis machine
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Uvadex
Generic name:	8- methoxypsoralen

Ethics review

Approved WMO

Date:	02-01-2008
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	EUCTR2005-004202-87-NL
CCMO	NL18842.029.07