Single arm study to assess comprehensive infusion guidance for the management of the infusion associated reaction (IARs) in Relapsing-Remitting Multiple Sclerosis (RRMS) patients treated with Lemtrada.

Published: 30-06-2014
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The objective of this study is to assess the distribution of infusion associated reactions (IARs) by severity grade when Lemtrada is administered to RRMS patients who will be medicated according to specified algorithm designed to manage infusion...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON40753

Source
ToetsingOnline

Brief title
EMERALD

Condition

- Demyelinating disorders

Synonym
MS, multiple sclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Genzyme
Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: infusion associated reactions, lemtrada, multiple sclerosis, open label

Outcome measures

Primary outcome

The distribution of IARs based on toxicity grade (severity) observed in the

study for both periods of treatment.

An IAR is defined as any adverse event occurring during or within 24 hours of

LEMTRADA infusion. Toxicity grade (severity) of IAR is based on Common

Terminology Criteria for Adverse Events (CTCAE)

The primary objective will be assessed by summarizing:

* Number (%) of IARs

* Number (%) and type of serious IARs

* Number (%) by type (as defined by clinical symptoms)

Secondary outcome

Not applicable.

Study description

Background summary

Multiple sclerosis (MS) is a demyelinating disease of the central nervous

system (CNS) that affects approximately 2.5 million people worldwide.
MS represents the leading cause of neurologic disability in young and middle-aged adults. It isestimated that as many as 80% of all MS patients present with relapsing remitting MS (RRMS).
LEMTRADA, is a humanized monoclonal antibody administered intravenously that has been approved in the European Union for the treatment of active RRMS.

Study objective

The objective of this study is to assess the distribution of infusion associated reactions (IARs) by severity grade when Lemtrada is administered to RRMS patients who will be medicated according to specified algorithm designed to manage infusion associated reactions.

Study design

Multicenter, multinational, phase 4 single arm open-label study.

Intervention

Drug: alemtuzumab (GZ402673, Lemtrada); Pharmaceutical form: Concentrate for solution for infusion; Route of administration: intravenous.

Study burden and risks

Identified risks of LEMTRADA in patients with MS include:
- Autoimmunity (ITP, nephropathies, thyroid disorders)
- Infections
- Infusion-associated reactions (IARs)

Contacts

Public
Genzyme

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NL
Scientific
Genzyme

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult RRMS patients who will be initiating treatment with Lemtrada according to local approved label
- Signed written informed consent

Exclusion criteria

- Previously treated with Lemtrada
- Contraindications to Lemtrada according to the labeling in the country
- Any known contraindications to the symptomatic therapy used in the infusion management guidance based on their local approved label
- Currently participating in another investigational interventional study
- Any technical/administrative reason that makes it impossible to enroll the patient in the study
- Patient is the Investigator or any Sub-investigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the protocol
- Patient who has withdrawn consent before enrollment (starting from signed informed consent form)
- Despite screening of the patient, enrolment is stopped at the study level
- Woman of childbearing potential not protected by highly-effective method(s) of birth control (as defined in a local protocol amendment in case of specific local requirement) and/or who are unwilling or unable to be tested for pregnancy
- Pregnancy (defined as positive beta-HumanChorionicGonadotropin blood test), breast feeding
- Known infection with latent tuberculosis or active Tuberculosis
- Known infection with Hepatitis B, Hepatitis C

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2014
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lemtrada
Generic name:	alemtuzumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-06-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-09-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-02-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-09-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2014-000092-62-NL
ClinicalTrials.gov	NCT00930553

Register	ID
CCMO	NL49717.060.14