A Multi-center, Open-label, Single-arm, Before and After Switch Study to Evaluate the Efficacy, Safety and Tolerability of Alemtuzumab in Pediatric Patients with Relapsing Remitting Multiple Sclerosis (RRMS) with Disease Activity on Prior Disease Modifying Therapy (DMT)

Published: 11-05-2017
Last updated: 13-04-2024

Primary objective:To evaluate the efficacy, safety and tolerability of alemtuzumab intravenously (IV) in paediatric patients from 10 to

Ethical review	Approved WMO
Status	Will not start
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON49585

Source
ToetsingOnline

Brief title
LEMKIDS

Condition

- Demyelinating disorders

Synonym

demyelinating disease, Multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: Genzyme Europe B.V.

Intervention

Keyword: Children, Efficacy, Multiple sclerosis, Phase III

Outcome measures

Primary outcome

The number of new or enlarging T2 lesions on brain MRI, during continuation of prior DMT (Period 1) compared to an equal period after the first course of alemtuzumab treatment (Period 2).

Secondary outcome

* Number of patients with new or enlarging T2 lesions during continuation of prior DMT (Period 1) compared to an equal period after the first course of alemtuzumab treatment (Period 2)

* Annualized relapse rate

* Assessment of cognition test scores through Brief Visuospatial Memory Test

* Assessment of generic pediatric QoL measures

* Assessment of PK parameters

* Assessment of PD parameter

* Number of patients with adverse events

* Assessment of development of anti-alemtuzumab antibodies

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 repesents the leading cause of neurologic disability in young and middle-aged adults. Multiple sclerosis is typically considered to be a disease of young adults. However, pediatric MS, defined as onset of MS before the age of 16, is increasingly recognized and accounts for approximately 5 percent of the cases.

Study objective

Primary objective:

To evaluate the efficacy, safety and tolerability of alemtuzumab intravenously (IV) in paediatric patients from 10 to <18 years of age with relapsing remitting multiple sclerosis (RRMS) who have disease activity on prior disease modifying treatmetn (DMT).

Secondary objective:

To assess the pharmacokinetics (PK), pharmacodynamics (PD), antidrug antibody formation, and potential effects of alemtuzumab on other multiple sclerosis (MS) disease characteristics such as cognition and quality of life (QoL).

Study design

A phase III, multi-center, open-label, single-arm study, before and after switch of DMT to alemtuzumab.

Intervention

Two doses of intravenous (IV) infusion of alemtuzumab.

Dose 1 (initial course) of alemtuzumab will be administered intravenously on 5 consecutive days, followed by Dose 2 (second course) on 3 consecutive days administered 12 months after initial course.

Study burden and risks

Risks and burdens related to blood collection, study procedures and possible adverse events of study medication.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

-Patients with RRMS aged from 10 years to less than 18 years at study entry are eligible. Patients must meet the criteria of diagnosis of MS as defined by the International Pediatric Multiple Sclerosis Study Group (IPMSSG) criteria for pediatric MS and the criteria of MS based on McDonald criteria 2010.
-Signed informed consent/assent obtained from patient and patient*s legal representative (parent or guardian) according to local regulations.
-Expanded Disability Status Scale (EDSS) score of 0.0 to 5.0 (inclusive) at screening.
-At least 2 recorded MS attacks and at least 1 MS attack (relapse) in the last year during treatment with a interferon-beta (IFNB) or glatiramer acetate (GA) after having been on that therapy for at least 6 months

-At least 1 of the following:
-*1 new or enlarging T2 hyperintense lesion or gadolinium enhancing lesion* while on that same prior therapy (IFNB or GA), OR
-Two or more relapses in the prior year, OR
-Tried at least 2 MS DMTs.

Exclusion criteria

-Any prior exposure to alemtuzumab.
-Any progressive or nonrelapsing form of MS.
-Treatment with natalizumab, daclizumab, fingolimod, methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil in the last 6 months, or as determined by the treating physician to have residual immune suppression from these or other MS treatments.
-Treatment with teriflunomide in the last 12 months except if the patient underwent the accelerated elimination procedure as per local teriflunomide label.
-Previous treatment with mitoxantrone, cyclophosphamide, cladribine, rituximab, ocrelizumab, leflunomide or any cytotoxic therapy.
-CD4+, CD8+, or CD19+ absolute cell count in blood at screening below lower limit of normal (LLN).
-Prior documented history of thrombocytopenia, or platelet count at screening

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	11-05-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-04-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-02-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	18-10-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-02-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-02-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
Other	2016-003100-30
EudraCT	EUCTR2016-003100-30-NL
CCMO	NL60747.078.17