Multiple Sclerosis treatment with Autologous Hematopoietic Stem Cell Transplantation (MS-ACT): A long-term prospective observational study in the Netherlands

Published: 25-08-2023
Last updated: 18-01-2025

To perform long-term pre-specified follow-up of patients undergoing aHSCT for refractory RRMS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON53285

Source
ToetsingOnline

Brief title
MS-ACT

Condition

- Autoimmune disorders
- Demyelinating disorders

Synonym
MS, Multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Annie van Coeverden

Intervention

Keyword: Autologous Hematopoietic Stem Cell Transplantation, Multiple sclerosis

Outcome measures

Primary outcome

Patients will be subjected to frequent visits with clinical, radiological and

biomarker follow-up until five years after aHSCT (primary phase and extension

phase). During these visits, clinical testing, evaluation by questionnaires,

MRI scans and blood sampling will be performed.

The main study parameters are: 1. no evidence of disease activity (meaning no

MS relapses, no disability progression and no MS MRI activity, i.e. NEDA3)

Secondary outcome

Secundary study parameters are safety and tolerability of aHSCT, biomarkers and

longitudinal analysis of immune reconstitution.

Study description

Background summary

In December 2022, autologous hematopoietic stem cell transplantation (aHSCT) was approved in the Netherlands for reimbursement for patients with treatment refractory relapsing remitting multiple sclerosis (RRMS). The Dutch Healthcare institute (*Zorginstituut Nederland: ZIN*) requested research of the outcomes of aHSCT for this indication.

Study objective

To perform long-term pre-specified follow-up of patients undergoing aHSCT for refractory RRMS.

Study design

This is a multicenter, prospective, long-term observational study.

Study burden and risks

Patients will be subjected to frequent visits after aHSCT. Follow-up after aHSCT in this study is more comprehensive than it would be in standard care (longer MRI protocols, more extensive laboratory measures and biobanking, more frequent clinical assessments).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

All patients who undergo aHSCT for the treatment of RRMS in the Netherlands are eligible to participate in this observational study.

Exclusion criteria

The only exclusion criteria for this observational study is unwillingness to participate or to sign informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-09-2023
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2023
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
CCMO	NL83783.018.23