Plerixafor and G-CSF for the Mobilisation of Peripheral Blood Stem Cells for Autologous Stem Cell Transplantation in Patients with Non-Hodgkin*s Lymphoma (NHL), Hodgkin*s Disease (HD) or Multiple Myeloma (MM) * Safety Study in a General Autologous Transplant Population

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Primary Objective: * To confirm the safety profile of plerixafor to mobilise stem cells when used in patients with lymphoma or MM who are eligible to undergo treatment with an autologous haematopoietic stem cell transplantSecondary Objectives:* To...

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

Summary

ID

NL-OMON32383

Source
ToetsingOnline

Brief title
MOZ00808

Condition

- Other condition
- Lymphomas non-Hodgkin's unspecified histology

Synonym
cancer of the blood, Kahler`s disease

Health condition

In aanvulling op bovenstaande: Multipel myeloom, ziekte van Hodgkin

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Autologous transplant, Mobilisation, Plerixafor, Stem cells

Outcome measures

Primary outcome

Patient safety will be assessed based on clinical laboratory evaluations and monitoring of AEs. The investigator will grade AEs using the NCI CTCAE version 3.0.

Adverse events will be recorded as follows:

* During the screening period (from signing consent form to first dose of G-CSF), only AEs related to study procedures will be recorded.

* All grade 3 and 4 AEs and all serious adverse events (SAEs) that occur from the first dose of G-CSF up to 30 days after the last dose of plerixafor or the first dose of myeloablative chemotherapy, whichever occurs first, will be documented.

* Any AE regardless of grade that occurs during the immediate post-injection

time period (30 minutes to 1 hour after plerixafor injection) will be recorded.

* Any AE, regardless of grade, that results in permanent discontinuation of plerixafor during the mobilization period will be recorded.

* Any SAE that occurs after the 30-day follow-up period that comes to the attention of the site staff that may be causally related to study drug must be reported to the Sponsor regardless of time elapsed.

* Any grade 3 and 4, study drug related AE or any SAE is to be followed until resolution, return to baseline, or until mutually agreed upon by both the Investigator and the Sponsor*s safety physician to discontinue.

* Disease progression, graft failure and/or death will be reported as SAEs for up to 12 months post transplant.

Secondary outcome

Efficacy:

* Number of days to neutrophil engraftment and platelet engraftment

* Increase in number of circulating CD34+ cells from time 0 to 10-11 hours after the first dose of plerixafor

* Total number of CD34+ cells collected by disease type

* Total number of CD34+ cells collected per apheresis day

* Graft status (as measured by trilineage counts and supportive treatment, e.g., transfusion, G-CSF) at 100 days, 6 months, and 12 months following transplant

The statistical analysis plan will provide the details on any additional analyses, e.g., the proportion of patients achieving at least 5 × 106 CD34+

cells.

Study description

Background summary

Using plerixafor together with G-CSF for the mobilization of stem cells, might enhance the mobilization of stem cells. This potentially enables collection of a sufficient amount of stem cells for tranplantation within less apheresis procedures.
This indicates for the patient that less apheresis days (days in the hospital) are needed to collect more cells.

Plerixafor could also increase the predictability of succesfull timing of the mobilization and collection of stem cells. This indicates that the autologous transplantations could be scheduled more efficient which would optimize the logistical planning within an institute.

Study objective

Primary Objective:
* To confirm the safety profile of plerixafor to mobilise stem cells when used in patients with lymphoma or MM who are eligible to undergo treatment with an autologous haematopoietic stem cell transplant

Secondary Objectives:
* To assess efficacy of plerixafor and granulocyte-colony stimulating factor (G-CSF) as a mobilisation regimen as measured by the number of CD34+ cells collected in each apheresis session
* To assess the clinical effectiveness of plerixafor and G-CSF mobilised stem cells by examining haematopoietic cell engraftment and graft status
* To examine the influence of CD34+ cell dose infused on time to engraftment, engraftment and graft status

Study design

This is a multi-centre, open label, single-arm study.

Plerixafor (240 mcg/kg) and G-CSF (10 mcg/kg/day, non-pegylated form) will be administered subcutaneously (SC) to the patients.

Day 1-4: G-CSF (10 mcg/kg/day) will be administered for 4 consecutive days in the morning.
Day 4: The plerixafor dose (240 mcg/kg) will be timed to allow for a 10- to

11-hour interval between the plerixafor dosing and the initiation of apheresis.
Day 5: Patients will receive a morning dose of G-CSF (10 mcg/kg) approximately 1 hour prior to apheresis.

Patients may continue to receive the evening dose of plerixafor then G-CSF the next morning followed by apheresis for up to a total of 5 apheresis procedures.

Prior to the first administration of plerixafor (on Day 4) and prior to administration of G-CSF for the first day of apheresis (on Day 5), the patient will have peripheral blood samples collected for determining the number of CD34+ cells in the peripheral blood. In addition, a sample will be obtained from each apheresis product to determine the quantity of CD34+ cells collected after each procedure.

Following the last apheresis, patients will undergo pre-transplant myeloablative chemotherapy followed by transplantation of the collected autologous stem cells, using the established protocols and procedures at each site. Subsequently, the patients will be monitored for graft status at 100 days, 6 months, and 12 months.

Intervention

Day 1-4: G-CSF 10 mcg/kg/day SC (non-pegylated form) will be administered in the morning.
Day 4: The plerixafor dose 240 mcg/kg SC will be timed to allow for a 10- to 11-hour interval between the plerixafor dosing and the initiation of apheresis.
Day 5: Patients will receive a morning dose of G-CSF (10 mcg/kg) SC approximately 1 hour prior to apheresis.

Study burden and risks

Please refer to section E for the nature and extent of the burden and risks associated with participation, benefit and grooup relatedness.

Contacts

Public
Genzyme

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Diagnosis of MM, NHL, or HD in partial response (PR) or complete response (CR)
2.Eligible and planned for an autologous haematopoietic stem cell transplantation
4.At least 18 years of age (inclusive)

Exclusion criteria

1. History of any acute or chronic leukaemia (including myelodysplastic syndrome)
2. Prior allogeneic transplantation or more than one prior autologous transplantation
3. Failed previous CD34+ cell collection attempts (either due to insufficient yield in apheresis product, or ineligible for apheresis because of inadequate mobilisation of CD34+ cells into peripheral blood)
4. Less than 4 weeks since last anti-cancer therapy (including chemotherapy, biologic/immunologic, radiation) or less than 6 weeks if prior therapy with nitrosourea or mitomycin (for therapies with long-acting agents, a treatment-free interval of at least 2 half-lives should be considered) with the exception of
- Treatment with thalidomide, dexamethasone, lenalidomide (Revlimid*), and/or bortezomib (Velcade*) which is allowed up to 7 days prior to the first dose of G-CSF.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	4
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	Plerixafor

Ethics review

Approved WMO Date:	25-08-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-08-2009
Application type:	Amendment

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	EUCTR2008-000689-21-NL
CCMO	NL23836.029.08