Randomized controlled trial on the effect of vitamin C supplementation in autologous stem cell transplantations

Published: 12-11-2018
Last updated: 10-01-2025

The aim of this study is to examine the effect of vitamin C supplementation on immune recovery in patients with autologous stem cell transplantation. The aim of the run-in phase of the study is to examine the effect of intravenous vitamin C...

Ethical review	Approved WMO
Status	Completed
Health condition type	Lymphomas non-Hodgkin's unspecified histology
Study type	Interventional

Summary

ID

NL-OMON55772

Source
ToetsingOnline

Brief title
Effect of vitamin C in autologous stem cell transplantations

Condition

- Lymphomas non-Hodgkin's unspecified histology
- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
lymphoma, multiple myeloma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ascorbic acid, autologous, stem cell transplantation, vitamin C

Outcome measures

Primary outcome

Primary endpoints will be AA plasma level on day 14 (run-in phase) and the day of neutrophil recovery after stem cell transplantation (randomized-controlled phase).

Secondary outcome

Secondary endpoints will be AA leukocyte levels, infection rate, duration of hospital stay, side effects of chemotherapy, overall survival, coagulation parameters, platelet reactivity, fibrinolysis and quality of life.

Study description

Background summary

Recent studies showed that ascorbic acid (AA) stimulates proliferation and maturation of T lymphocytes and NK cells. Chemotherapy results in depletion of those cells and thereby an increased infection rate. A pilot study showed low levels of AA in the plasma of several patients after chemotherapy followed by autologous stem cell transplantation for hematological malignancies. AA supplementation could be beneficial to the recovery of the immune system in these patients.

Study objective

The aim of this study is to examine the effect of vitamin C supplementation on immune recovery in patients with autologous stem cell transplantation. The aim of the run-in phase of the study is to examine the effect of intravenous vitamin C supplementation on plasma concentrations of vitamin C in patients with autologous stem cell transplantation at day 14 in order to be sure that in the intervention study accurate AA plasma levels will be present.

Study design

run-in phase, followed by randomized controlled trial

Intervention

Vitamin C intravenous during 2-3 weeks followed by oral vitamin C for a total of six weeks.

Study burden and risks

AA supplementation could be beneficial for the immune recovery in the participants of this study. The risks associated with participation in this study are low. Vitamin C supplementation is safe and hardly has any documented side effects.

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

- 18 years or older
- written informed consent
- diagnosis of malignant lymphoma or multiple myeloma
- require chemotherapy plus autologous stem cell transplantation
- central venous catheter in place or planned

Exclusion criteria

- inability to understand the nature and extent of the trial and the procedures required
- history of kidney stones
- kidney failure requiring dialysis or eGFR <30 mL/min. (CDK-EPI formula)
- history of G6PD deficiency
- life expectancy < 1 month
- use of immunosuppressive medication other than chemotherapy and corticosteroids
- active vitamin C supplementation other than normal daily multivitamin use
- any concurrent medical or psychiatric condition or disease that is likely to interfere with the study procedures or results, or that in the opinion of the investigator would constitute a hazard for participating in this study.
- Patients that are eligible after transplantation for a follow up in the out-patient setting and want to use this option.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-05-2019
Enrollment:	47
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ascorbic acid
Generic name:	ascorbic acid
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	12-11-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-04-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2018-004135-77-NL
CCMO	NL68010.068.18

Study results

Date completed: 21-02-2022

Results posted: 06-12-2022

First publication
01-01-1900