Frozen gloves for prevention of chemotherapy-induced peripheral neuropathy

Published: 01-11-2012
Last updated: 26-04-2024

The primary objective is to evaluate the effectivity of frozen gloves during chemotherapy in the prevention of neurotoxicity and thereby the influence on the quality of life in patients treated with oxaliplatin, paclitaxel or docetaxel.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON40077

Source
ToetsingOnline

Brief title
Frozen gloves for chemotherapy-induced neurotoxicity

Condition

- Peripheral neuropathies

Synonym
chemotherapy-induced neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: subsidie via stichting Máxima wordt aangevraagd

Intervention

Keyword: chemotherapy, neuropathy, neurotoxicity, prevention

Outcome measures

Primary outcome

Main study parameters/endpoints:

Quality of life and neuropathy symptoms are measured with the validated European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire (EORCT-QLQ) and with the validated CIPN20 self-report questionnaire respectively at four time points (begin study, after three cycles, end of chemotherapy and after 6 months).

Secondary outcome

Secundary objectives of the study are;

1) The degree of tolerance for the use of the frozen gloves measured with the numering rating scale (NRS)

2) Dose reduction due to neurotoxicity.

3) Difference in neurotoxicity expressed in the common toxicity criteria (CTC).

4) Clustering of symptoms: do patients also have complaints in the feet and are these similar to complaints of the hands?

Study description

Background summary

Rationale: Chemotherapy-induced peripheral neuropathy (CIPN) is a common major dose-limiting side effect of many chemotherapeutic agents. CIPN leads to a significant decrease in patient*s quality of life. Using frozen gloves during chemotherapy could probably be used to prevent CIPN.

Study objective

The primary objective is to evaluate the effectivity of frozen gloves during chemotherapy in the prevention of neurotoxicity and thereby the influence on the quality of life in patients treated with oxaliplatin, paclitaxel or docetaxel.

Study design

Study design: randomized controlled trial, open
Intervention (if applicable): Frozen gloves.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be asked to fill in a questionnaire at different time points, that will take half an hour extra. Frozen gloves will be used during chemotherapy, no extra visits are needed, however an extra half an hour is required as the frozen gloves have to be worn 15 before initiation of the infusion until 15 minutes after the end of the infusion. There are no studies carried out showing adverse effects of using frozen gloves. A side-effect could be cold intolerance.

Contacts

Public
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Written informed consent
• Patients aged > 18 years
• All cancer patients starting with paclitaxel, docetaxel or oxaliplatin
• Understand Dutch language

Exclusion criteria

• Patients with reported pre-existing neuropathy
• Patients with cold intolerance
• Patients with Raynaud*s syndrome
• Patients earlier treated with paclitaxel, docetaxel or oxaliplatin
• Patients using scalp cooling
• Short-term chemoradiation with paclitaxel, docetaxel or oxaliplatin

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2013
Enrollment:	140
Type:	Actual

Medical products/devices used

Generic name:	frozen glove
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-11-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-01-2013
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-05-2013
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-02-2014
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL39650.015.12