

Frozen Gloves in the prevention of polyneuropathy

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The goal of this study is to examine the effect of cooling on neuropathy in the hands of patients who are treated with Paclitaxel, Docetaxel en Oxaliplatin. Patients who will be included in the study are those who start with chemotherapy. The...

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

Summary

ID

NL-OMON35073

Source

ToetsingOnline

Brief title

Frozen Gloves in the prevention of polyneuropathy

Condition

- Peripheral neuropathies

Synonym

loss of sensation in limbs, Polyneuropathy

Research involving

Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: MMC Veldhoven;interne geneeskunde

Intervention

Keyword: Chemotherapy, Hand cooling, Polyneuropathy, Quality of Life

Outcome measures

Primary outcome

Neuropathy in the hands.

Secondary outcome

Not relevant.

Study description

Background summary

Even after a lot of investigation there still isn't a good prophylaxis found for neuropathy due to chemotherapy.

There is no literature available about the influence of cooling on polyneuropathy.

Study objective

The goal of this study is to examine the effect of cooling on neuropathy in the hands of patients who are treated with Paclitaxel, Docetaxel en Oxaliplatin. Patients who will be included in the study are those who start with chemotherapy. The preventive effect of cooling on neuropathy will be evaluated.

Study design

Control study, one hand will be cooled using a Frozen Glove, the other hand is the control. Two questionnaires will be used to examine the seriousness of the neuropathy. We will use the Cinq and the FACT/GOG/Ntx.

Intervention

Apply the frozen glove during chemotherapy.

Study burden and risks

Not relevant.

Contacts

Public

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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

Chemotherapy treatment with paclitaxel, docetaxel or oxaliplatin

Exclusion criteria

Rheumatic Arthritis

Raynaud syndrom

Previous treatment with neurotoxic cytostatics

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2009
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	09-03-2010
Application type:	First submission
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

CCMO

ID

NL29866.015.09