Randomized controlled trial of controlled hand/foot cooling to prevent neuropathy and preserve quality of life in adults treated with oxaliplatin.

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This randomized phase II open label study examines the effect of controlled cooling versus no cooling on the incidence and severity of oxaliplatin-induced peripheral neuropathy (OIPN) in patients treated with oxaliplatin.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON56750

Source
ToetsingOnline

Brief title
OIPN research into controlled hand/foot cooling with Oxaliplatin

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Peripheral neuropathies

Synonym
nerve damage, peripheral neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Tergooiziekenhuizen
Source(s) of monetary or material Support: Zowel Stichting Vaillantfonds als Vrienden van Tergooi hebben geld beschikbaar gesteld voor in totaal twee hand/voetkoelapparaten. Deze koelapparaten zullen gebruikt worden voor de uitvoer van deze studie en daarna voor reguliere patiëntenzorg. Hierdoor fungeren zij enkel als sponsoren ter financiering van de apparaten voor de OIPN studie en zijn zij niet betrokken bij de uitvoering van de studie. Daardoor geldt dat er voor beide sponsoren geen sprake is van belangenverstrengeling ten aanzien van de studie.

Intervention

Keyword: controlled hand/foot cooling, neuropathy, nursing sciences research, Oxaliplatin

Outcome measures

Primary outcome

The difference in average relative dose intensity (expressed as a percentage of

the starting dose) of oxaliplatin in the control group compared to the

intervention group.

Secondary outcome

The scores of CIPN and EORTC QLQ-C30 scores are assessed for normality by

visually checking the difference scores with a histogram, and testing whether

the difference scores are normally distributed with the Shapiro-Wilk test. If

the data are normally distributed, the scores are compared with an unpaired

t-test. If the data are not normally distributed, the Mann-Whitney test is

used.

Study description

Background summary

A small-scale study recently proved that preventive controlled cooling can lead

to a decrease in chemotherapy-induced polyneuropathy (CIPN) in the hands and feet, thereby preserving quality of life. Tergooi MC is the first hospital in the Netherlands to include preventive controlled cooling as a standard treatment for treatment with taxanes.

For treatment with oxaliplatin, there has recently been limited data that controlled cooling can also reduce CIPN with this treatment. However, this has only been proven in 1 small study and not in another independent cohort. This randomized phase II open label study examines the effect of controlled cooling versus no cooling on the incidence and severity of oxaliplatin-induced peripheral neuropathy (OIPN) in patients treated with oxaliplatin.

Study objective

This randomized phase II open label study examines the effect of controlled cooling versus no cooling on the incidence and severity of oxaliplatin-induced peripheral neuropathy (OIPN) in patients treated with oxaliplatin.

Study design

The design of the study is a phase II open-label randomized controlled trial. This research is carried out according to the GCP quality standard. Patients eligible for treatment with oxaliplatin are asked to participate in the study. With a randomization algorithm in Castor CDMS, patients are assigned to either the intervention group or the control group (1:1 randomization stratification will be based on oxaliplatin treatment schedule (80mg/m2 q2w versus 130mg/m2 q3w).).
Similar to the study by Coolbrandt et al. (https://doi.org/10.1016/j.esmoop.2023.101205), controlled cooling takes place in the intervention group 30 minutes before the start, during running in and 30 minutes after running in the oxaliplatin.

Intervention

One group does not receive hand/foot cooling, one group receives controlled hand/foot cooling

Study burden and risks

Risk of controlled hand/foot cooling is minimal.

Contacts

Public

Tergooiziekenhuizen

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Tergooiziekenhuizen

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Treatment with oxaliplatin

Exclusion criteria

Presence of neuropathie before start treatment oxaliplatin;
previous chemotherapy treatment;
palliative treatment of pancreas- or stomachcarcinoma;
Raynaud's phenomenon
Cold-related conditions, including cryoglobulinemia, cold hemagglutination and cold urticaria

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2024
Enrollment:	90
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	08-05-2024
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	NL85337.018.23