Prospective, multi-centre trial to evaluate effectiveness of 45-min and 20-min post-infusion cooling time for patients treated with scalp cooling to prevent paclitaxel-induced alopecia

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Evaluate the effectiveness of 45- and 20-minutes post-infusion cooling time for scalp cooling in patients treated with paclitaxel in comparison with the standard post-infusion cooling time of 90-minutes

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

Summary

ID

NL-OMON44353

Source
ToetsingOnline

Brief title
COP

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chemotherapy-induced alopecia, Paclitaxel, Post-infusion cooling time, Scalp cooling

Outcome measures

Primary outcome

To determine the efficacy of scalp cooling in patients treated with

paclitaxel-containing chemotherapy with a 45- and 20-minutes post-infusion

cooling time, in comparison with the standard 90 minutes and no scalp cooling,

defined by the patient*s self-determined need to wear a wig or other head

covering

Secondary outcome

* To determine the degree of chemotherapy-induced alopecia (CIA), assessed with

the Dean scale for assessment of hair loss

* To determine the grade of alopecia according to NCI CTCAE toxicity version

4.03

* To determine the tolerance of scalp cooling, assessed by a (self-adapted)

visual analogue scale (VAS) of 0-10, in which 0 represented *not tolerable at

all* and 10 meant *very tolerable*

* To determine the added value of scalp cooling for weekly paclitaxel; what is

the incidence of severe alopecia with and without scalp cooling

* Compare the quality of life in patients who underwent scalp cooling versus

those who did not and in patients with hair loss despite scalp cooling versus

those with no hair loss, assed with the chemotherapy-induced alopecia distress

scale (CADS)

Study description

Background summary

Chemotherapy-induced alopecia (CIA) is one of the most distressing side effects for patients. Scalp cooling can prevent or minimise CIA in approximately half of all patients, depending on many factors, e.g. type and dosage of chemotherapy. High rates of success are seen in patients treated with taxanes, up to 80-90%. Previous research has shown comparable results of scalp cooling in docetaxel-treated patients when shortening the post-infusion cooling time (PICT) from the initial standard of 90 minutes to 45- and 20 minutes. A shorter PICT is an advantage for both the patient, who can spend less time in the hospital, as well for the logistics at oncological departments. Paclitaxel and docetaxel are both classical taxanes, thatwho share similar mechanisms of action and have comparable plasma terminal half-life times, therefore it seems plausible that the PICT can be shortened for paclitaxel-treated patients as well.

Study objective

Evaluate the effectiveness of 45- and 20-minutes post-infusion cooling time for scalp cooling in patients treated with paclitaxel in comparison with the standard post-infusion cooling time of 90-minutes

Study design

The study is a prospective, multicenter trial, in which consecutively a PICT of 45- and 20 minutes will be investigated in patients treated with paclitaxel.

Patients who chooses scalp cooling will be randomly assigned to a treatment arm of 45- or 20-minutes PICT. If the patient does not want scalp cooling, the patient will be asked for the control group to determine the incidence of paclitaxel-induced alopecia.
The results from a PICT of 45- and 20-minutes will be compared with the standard PICT of 90-minutes, using previous collected data from the Dutch Scalp Cooling Registry. In which 377 patients are registered who received weekly paclitaxel and underwent scalp cooling with a PICT of 90 minutes.

Intervention

Randomisation between a 45- and 20-minutes post-infusion cooling time

Study burden and risks

Scalp cooling is nowadays a non-experimental, and frequently used, supportive care intervention in Dutch hospitals. Previous research showed that scalp cooling is safe and well tolerable. Shortening the post-infusion cooling time, the experimental factor in our study, is not associated with an additional risk for patients. There is at the most, a slightly increased chance of CIA, which can lead to psychological discomfort. The questionnaires which have to be filled in each cycle of chemotherapy take about 5 minutes to complete. All scalp cooled patients who participate in this study will benefit from a shorter stay on the chemotherapy ward. Non-scalp cooled patients will not have any advantage, neither disadvantage.

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

* Patients receiving weekly-administered paclitaxel-containing chemotherapy (minimal of 3 planned administrations) in a dose of 80-90 mg/m2
o Paclitaxel monotherapy
o Paclitaxel in combination with carboplatin
o Paclitaxel in combination with monoclonal antibodies:
* Bevacizumab
* Trastuzumab
* Age * 18 years
* WHO performance status 0-2
* Survival expectation must be > 3 months
* Written informed consent according to the local Ethics Committee requirements

Exclusion criteria

* Treatment with paclitaxel in sequential schemes with other alopecia inducing agents such as (paclitaxel monotherapy after adriamycin, cyclophosphamide (AC) or paclitaxel monotherapy after 5-fluouracil, epirubicin, cyclophosphamide (FEC) treatment)
* Alopecia before the start of the study
* Rare cold-related disorders, like:
o Cold sensitivity
o Cold agglutinin disease
o Cryoglobulinaemia
o Cryofibrinogenaemia
o Cold posttraumatic dystrophy

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-01-2018
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL61964.058.17