Effects of scalp cooling on pharmacokinetics of paclitaxel in women treated for advanced cancer

Published: 22-12-2015
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To study whether the pharmacokinetics of paclitaxel are influenced by scalp cooling

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON44910

Source
ToetsingOnline

Brief title
Influence of scalp cooling on paclitaxel PK

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
advanced carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Subsidie Coolsingel Stichting

Intervention

Keyword: paclitaxel, pharmacokinetics, scalp cooling

Outcome measures

Primary outcome

Difference in pharmacokinetics of paclitaxel (AUC, e.g. the exposure to paclitaxel in blood) between patients who undergo scalp cooling during their anti-cancer treatment versus those patients, who did not undergo scalp cooling during their anti-cancer treatment

Secondary outcome

Difference in pharmacokinetics of paclitaxel (AUC, e.g. the exposure to paclitaxel in blood) between patients who do and who do not develop boldness during the use of scalp cooling and their anti-cancer treatment. If this is clinically relevant, other pharmacokinetic parameters will be studied, such as clearance.

Study description

Background summary

Chemotherapy-induced hair loss is a feared side effect of cancer treatment. Scalp cooling during the administration of cytotoxic drugs can reduce this hair loss, with a good chance of success depending on the type of chemotherapy that is used. For the cytotoxic drug paclitaxel it is often successful. Although scalp cooling is regularly used, it is unknown whether scalp cooling has effects on the concentration of chemotherapy in the blood. In this project, we will study the effect of scalp cooling on the concentration of paclitaxel in blood.

Study objective

To study whether the pharmacokinetics of paclitaxel are influenced by scalp

cooling

Study design

36 patient have to be enrolled in this trial to have sufficient power for the primary endpoint (18 controls and 18 who undergo scalp cooling). The control-group exists of 25 patients, that means we have to enroll 14 patients who undergo scalp cooling to maintain power. The data from the control-group are already available from a previous trial.

During the administration of paclitaxel and the use of scalp cooling, pharmacokinetics will be measured during 1 day. If a patient stops with scalp cooling during their anti-cancer treatment, pharmacokinetics will be measured again in the case a patient gives permission to do so.

Study burden and risks

Patients will stay 6 hours longer at the outpatient clinic during one paclitaxel cycle. During this period blood withdrawals for pharmacokinetic purposes will be performed, which are accompanied by a negligible risk of bleeding or infection.

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

Histologically confirmed metastasized cancer and planned treatment with weekly paclitaxel
Women
Written informed consent
Age >= 18 years

Exclusion criteria

Boldness prior to treatment of the study
Serious psychiatric illness, confusion or intellectual disability
Hematologic malignancy
Cold sensitivity, cold agglutinin disease, cryoglobulinemia, cold post-traumatic dystrophy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2016
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52136.078.15