Measurement of superficial scalp skin temperature during scalp cooling as applied for prevention of hair loss due to chemotherapy.

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

Summary

ID

NL-OMON32056

Source
ToetsingOnline

Brief title
scalp skin temperature

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
NVT

Research involving
Human

Sponsors and support

Primary sponsor: W.P.M. Breed, Integraal Kankercentrum Zuid
Source(s) of monetary or material Support: niet van toepassing: geen kosten verbonden aan onderzoek

Intervention

Keyword: scalp cooling, scalp skin temperature

Outcome measures

Primary outcome

The temperature of the scalp skin during cooling with the recent and the new

cooling liquid and probably during air cooling

Secondary outcome

The degree of enduring during cooling with the recent and the new cooling

liquid and probably during air cooling.

The course of the bodytemperature during cooling with the new cooling liquid.

Study description

Background summary

For years already scalp cooling is applied during chemotherapy. Unfortunately it's not succesful with everyone. During scalp cooling with the Paxman cooler the scalp skin reaches with the present cooling liquid probable a temperature of 15-20°C . There is a pretty big interindividual spreading. The optimal temperature of the scalp skin to reach maximum hairprotection is unknown, but it is likely that maximum hairprotection is reached with more patients when the cooling liquid in the machine is a few degrees lower than is possible with the present cooling liquid. Therefore, the manufacturer has recently developed a new cooling liquid.

Study objective

The primary goal is to find out whether or not you can reach with the new cooling liquid in the Paxman cooler, and probably with air cooling, a ±5°C

lower temperature of the scalp skin.
The secundary goal is to find out how a possibly reached lower temperatur of the scalp skin is being endured. In addition the goal is to find out wether or not there is a drop in body temperature during scalp cooling.

Study design

This will be a pilot study. Ten healthy, voluntary subjects will be collected. They will be cooled once with the Paxman cooler with the recent cooling liquid, once with the new cooling liquid and maybe once with air cooling. The cooling time per session will be 90 minutes. By means of a temperaturemaesurement developed by the TU Eindhoven the temperature of the scalp skin will be maesured during the cooling. When the temperature is still decreasing between 60 and 85 minutes(>1°C), then the cooling time will be lengthened to 120 minutes.
The body temperature will be maesured by means of a earthermometer. In addition the central bodytemperature during cooling with the new liquid will be maesured at a few subject by means of a "pill". This "pill" is a temperaturesensor which can be swallowed. After four hours the "pill" is in the small intestine. By means of maesuring equipment the signals of the "pill" can be received and the central bodytemperature registered carefully. The "pill" leaves the body later via the stools. It has nog consequenses for the subject.
On the basis of a earlier clinical applied questionnaire the degree of enduring per cooling session will be watched.

Study burden and risks

There are no risks attached to participation and the expectation is that the degree of enduring will not be high:
At this moment a QoL-study is being performed under patients who are treated with scalp cooling. The results are yet not analysed and publiced. But it is known that when patients are asked how they endure cooling with the standard temperature, they score a 7,6 on a scale from 0-10, in which 0=not to endure and 10=very good to endure.
With 82%(n=572) of the cooling session no headache is being reported, with 14%(n=98) mild headache, with 3%(n=25) moderate headache and with 1%(n=10) heavy headache.
It is expected that the duration of the cooling will not be a problem for the subjects. There are namelijk chemotherapy courses, including Taxol, which have a entering time of 4 hours. With half an hour of precooling and one and a half hour of postcoolingtime, these patients are being cooled during 6 hours. Also the temperature of the cooling cap shouldn't be a problem. The machine has a constant temperature of -10°C. With this the scalp skin probably gets a temperature between 15 and 20°C. To get a scalp skin temperature between 10 and 15°C, the new cooling liquid will probably have to get a temperature of -15°C.
In the past cooling is being performed without any problems with cooling caps

from a freezer of -30°C, a substantial lower temperature than the temperature of the cooling liquid. This cap warmed up slowely indeed, but after every half hour the cap had to be replaced by a new cap of -30°C.

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

at least 18 years old

Exclusion criteria

Cold agglutinin disease

Cryoglobulinemia
Cryofibrinogenemia
Cold posttraumatic dystrophy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	12-11-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL20576.058.07