Muticentre study to investigate the efficacy of scalp cooling for the prevention of Myocet/cyclofosfamide-induced alopecia in patients with metastatic breast cancer. MyCap study

Published: 29-11-2011
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PrimaryTo assess the efficacy of scalp cooling in preventing allopecia due to Myocet chemotherapy by the objective method of trichometry. Secondary:* Assess the efficacy of scalp cooling by comparing the objective method (trichometry) with the...

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

Summary

ID

NL-OMON35380

Source
ToetsingOnline

Brief title
MyCap

Condition

- Other condition

Synonym
alopecia, hair loss

Health condition

haaruitval t.g.v. chemotherapie

Research involving
Human

Sponsors and support

Primary sponsor: Stichting DIADOC
Source(s) of monetary or material Support: Stichting DIADOC

Intervention

Keyword: alopecia, cyclophosphamide, Myocet, scalp cooling

Outcome measures

Primary outcome

Allopecia measured by trichometry.

Secondary outcome

Subjective severity of allopecia.

Study description

Background summary

Allopecia due to chemotherapy is for women with breast cancer one of the most burdenful adverse effects of the cancer treatment. The psycological inpact is considerable. Scalp cooling may be performed to reduce allopecia due to chemotherapy. In general scalp cooling results in a satisfactory result in 50% of cases. The efficacy of scalp cooling during chemotherapy with Myocet, de liposomal variant of doxorubicin, and cyclophosphamide has never been investigated. If effecive, this may result in a better quality of life.

Study objective

Primary
To assess the efficacy of scalp cooling in preventing allopecia due to Myocet chemotherapy by the objective method of trichometry.
Secondary:
* Assess the efficacy of scalp cooling by comparing the objective method (trichometry) with the subjective methods WHO score questionnaire and VAS rating.
* Assess th efficacy of scalp cooling by comparing the trichometry results with

the use of a wig or comparable.

Study design

Open, non-randomized parallel group phase IV pilot study.
After the decision to treat a patient for medical reasons with Myocet, the study and the option of scalp cooling will be discussed.
Those patients who choose to particpate and to perform scalp cooling, will be allocated to the experimental group (chemotherapy plus scalp cooling plus trichometry).
Those patients who choose to particpate and not to perform scalp cooling, will be allocated to the control group (chemotherapy plus trichometry).
Normally 6 courses of Myocet will be adminsitered. Scalp cooling will be performed during all cycles.
80 patients in total (40 in both groups), approx. 70 in NL.

Intervention

Treatment with or without scalp cooling. Trichometry.

Study burden and risks

Risk: In studies the generally good tolerabilty of scalp cooling had been shown. During the 1st 10 minutes scalp cooling is normally perceived as cold and sometimes unpleasant. Headache may occur, seldom severe and with a positive effect of pain killers.
In theory it is possible that small, not visible metastases on the scalp may be less accessible for chemotherapy due to the scalp cooling. Scal cooling is applied for 30 years now. The results of investigations in several thousands of patients have been reported. An increased frequency of metastases on the scalp or elsewere has not been reported. A less favorable course of the disease after scalp cooling has not been reported either.

Burden: Scalp cooling during every Myocet cycle. Extra visit duration per cycle: approx. 2h, incl. trichometry and completion of questionnaire re. allopecia and VAS rating.

Contacts

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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

* Female breast cancer patients, treated with Myocet and cyclophosphamide containing chemotherapy.
* Life expectancy * 12 weeks.
* ECOG performance scale * 2.
* Age 18 years and above.

Exclusion criteria

* Allopecia prior to start of the study.
* Simultaneously or shortly after study start: planned skull irradiation (if allopecia is expected).
* Severely disturbed liver enzymes (see protocol for details).
* Hair extensions

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2011
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-02-2012
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-03-2012
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-04-2012
Application type:	Amendment
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

ID: 23571
Source: NTR
Title:

In other registers

Register	ID
Other	Nederlandse Trial Register, registratienummer n.n.b.
CCMO	NL38226.015.11
OMON	NL-OMON23571