The effect of scalp cooling on alopecia during Myocet/cyclophosphamide chemotherapy.

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Alopecia (frequency and severity) induced by Myocet and cyclophosphamide will not be different compared to conventional doxorubicine and cyclophosphamide.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23571

Bron
Nationaal Trial Register

Verkorte titel
MyCap

Aandoening

chemotherapy-induced alopecia

Ondersteuning

Primaire sponsor: Stichting DIADOC
Overige ondersteuning: MSD (former Cephalon)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Allopecia measured by trichometry.

Toelichting onderzoek

Achtergrond van het onderzoek

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 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.

Patient population:

Female patients with metastatic breast cancer who will be treated with Myocet. 18 years and above.

Doel van het onderzoek

Alopecia (frequency and severity) induced by Myocet and cyclophosphamide will not be

different compared to conventional doxorubicine and cyclophosphamide.

Onderzoeksopzet

Every 3 weeks.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female breast cancer patients, treated with Myocet and cyclophosphamide containing chemotherapy;

2. Life expectancy >=12 weeks;

3. ECOG performance scale 2;

4. Age 18 years and above.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Allopecia prior to start of the study;

2. Simultaneously or shortly after study start: planned skull irradiation (if allopecia is expected);

3. Severely disturbed liver enzymes (see protocol for details);

4. Hair extensions.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35380
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3423
NTR-old	NTR3573
CCMO	NL38226.015.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35380

Resultaten

Samenvatting resultaten
N/A