Caphosol as a therapeutic option in patients with breast- or colorectal cancer at risk for chemotherapy-induced oral mucositis

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To evaluate the effectiveness of a calcium phosphate mouth rinse (Caphosol) on the burden of disease of moderate and severe oral mucositis (WHO scale grade II-IV). In breast cancer patients receiving FE90C x6 (q3w), FE100C x3 (q3w) followed with…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON38087

Source
ToetsingOnline

Brief title
TOPCOM

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
mucositis, stomatitis

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Eusapharma

Intervention

Keyword: breastcancer, caphosol, colorectal cancer, mucositis

Outcome measures

Primary outcome

To evaluate the effectiveness of a calcium phosphate mouth rinse (Caphosol) on

the burden of disease of moderate and severe oral mucositis (WHO scale grade

II-IV)

Secondary outcome

The effect of oral mucositis on planned chemotherapy dosing

The consumption of hospital resources used to treat oral mucositis

Study description

Background summary

Oral mucositis is a common side effect of drug and radiation therapy used for the treatment of cancer. Despite the fact that mucositis has long been known to be a complication of cancer therapy, the treatment options are limited. Caphosol a Calcium phosphate solution has been shown to improve patient quality of life and reduce the cost of treatment in a range of cancer patients. In this study the effectiveness of Caphosol in mamma and colon cancer regimes will be assessed.

Study objective

To evaluate the effectiveness of a calcium phosphate mouth rinse (Caphosol) on the burden of disease of moderate and severe oral mucositis (WHO scale grade II-IV). In breast cancer patients receiving FE90C x6 (q3w), FE100C x3 (q3w) followed with docetaxel x3 (q3w), TAC x6 (q3w) or FAC x6 (q3w). In colorectal cancer patients receiving FOLFOX-IV x9 (q2w) (+/- bevacizumab) or XelOx x8 (q3w) (+/- bevacizumab). By using written Oral Mucositis daily questionaires (10 days per cycle) and a questionair at the end of the cycle. Measured for 2

cycles.

Study design

Open label, randomized prospective evaluation of the effectiveness of a calcium phosphate mouth rinse in chemotherapy-induced oral mucositis in patients at risk. In breast cancer patients receiving FE90C x6 (q3w), FE100C x3 (q3w) followed with docetaxel x3 (q3w), TAC x6 (q3w) or FAC x6 (q3w). In colorectal cancer patients receiving FOLFOX-IV x9 (q2w) (+/- bevacizumab) or XelOx x8 (q3w) (+/- bevacizumab).
Patients developing clinical signs of oral mucositis (>grade 2 WHO) are likely to be subject to (more severe) mucositis in subsequent cycles of chemotherapy. Oral mucositis (> grade 2) will be assessed as an inclusion criterion in any of the first three cycles of chemotherapy when oral problems are evident.
Patients are randomized in a control arm receiving standard oral care alone or a treatment arm receiving Caphosol as an adjunct to good oral hygiene. Standard oral care includes good oral hygiene and local oral mucositis practice.
Caphosol is given according to manufacturer*s instructions.
To evaluate the burden of disease, following the clinical manifestation of > 2 grade oral mucositis, all patients will provide self-assessments from study days 1 to 10 (unless oral problems are still apparent) of 2 consecutive cycles of chemotherapy using the Oral Mucositis Daily Questionnaire (OMDQ). The OMDQ is composed of 8 questions in three categories: overall health, mouth and throat soreness (MTS) and diarrhea.

For patients hospitalized due to oral mucositis, hospital resources will be measured (nonopoid and opoid use, parenteral nutrition use, antimicrobial drugs use, length of hospital stay, hospital charges, consumption of blood products) and patient resources (cab fee, days off from work etc).

Patients will undergo all treatment procedures according to normal clinical practice. However, for inclusion no adjustment of chemotherapy dosages are allowed up till the chemotherapy cycle following the chemotherapy cycle in which oral mucositis > grade 2 is assessed. Per-protocol-patients will be offered Caphosol freely for the remaining period of the chemotherapy schedule.

Intervention

Caphosol will be used 4x daily according to manufactures description.

Study burden and risks

There is no risk involved with participation, patients need to fill in daily questionnaires, free Caphosol will be provided to treat and prevent Oral Mucositis.

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 18 years or older
* Patients first diagnosed with breast cancer receiving FE100C x6, FE100C x3 and docetaxel x3, TAC x6, FAC x6, AC x4 followed with Docetaxel x4, AC x4 followed with Docetaxel/Trastuzumab x4. Patients diagnosed with first colorectal cancer receiving FOLFOX-IV x9 (+/- bevacizumab), XelOx x8 (+/- bevacizumab)
* Patients with clinically assessed >grade 2 oral mucositis in any of the first three cycles of chemotherapy and that receive at least two subsequent chemotherapy cycles of the same therapeutic agent
* Willingness not to use marketed oral mucositis drugs, rinses or artificial saliva (Gelclair, Mugard, Evomucy, Biotene, Oral Balance, Magic Mouthwash) for 2 cycles when on standard oral care
* Written informed consent

Exclusion criteria

*Receiving palifermin
*Receiving low level laser therapy
*Dose adjustment in chemotherapy dosages up till the chemotherapy cycle following the chemotherapy cycle in which oral mucositis > grade 2 is assessed.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2012
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Caphosol
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-12-2011
Application type:	First submission

Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-09-2012
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	21-09-2012
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-04-2013
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

No registrations found.

In other registers

Register	ID
CCMO	NL37203.015.11