Phase III Randomized Double-Blind Trial of Bepanthen® Cream Versus Cetomacrogol Cream in the Prevention of Papulopustular eruption in Patients Receiving Epidermal Growth Factor Receptor Inhibitors (EGFRI): BeCet

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To assess the preemptive effect of Bepanthen® on decreasing the incidence of specific >= grade 2 dermatological side effects of interest in respect of compliance to EGFRI agents, HRQoL and the adherence during the 6-week skin treatment period....

Ethical review	Approved WMO
Status	Completed
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON39936

Source
ToetsingOnline

Brief title
BeCet

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Epidermal and dermal conditions

Synonym
dermatological side effects, skin toxicities

Research involving
Human

Sponsors and support

Primary sponsor: Stichting IMPAQTT
Source(s) of monetary or material Support: Bayer,Bayer;verstrekker studie creme (Bepanthen);fototoestellen en educational grant

Intervention

Keyword: adherence, dermatological side effects, epidermal growth factor receptor (EGFR), quality of life

Outcome measures

Primary outcome

1. The incidence of grade >= 2 papulopustular eruption during the 6 week skin

treatment within Bepanthen and Cetomacrogol, as measured by the CTCAE v4.0 and

DERETT-H, an dermatologic specific healthcare provider questionnaire for

Dermatological Reactions Targeted Therapy.

2. Assess the impact of papulopustular eruptions on HRQoL as measured by the

Functional Assessment of Cancer Therapy Questionnaire - EGFRI (FACT-EGFRI) and

newly developed symptom experience diary Dermatological Reactions Targeted

Therapy - Patients (DERETT-P).

Secondary outcome

3. Determine the patient tolerability and satisfaction of Bepanthen®/

Cetomacrogol cream as measured by DERETT-P.

4. Determine the effectiveness of Bepanthen® cream versus Cetomacrogol cream on

the adherence to anticancer agents as measured by FACT-EGFRI and DERETT-P.

5. Assessments during the 6-week skin treatment period of the incidence and

time to onset of other dermatological side effects which can appear together

with papulopustular eruptions as measured by DERETT-H.

Study description

Background summary

Dermatological side effects, such as papulopustular eruption, xerosis, pruritus, periungual inflammation, mucosal-, and hair abnormalities, and edema occur in up to 90% of patients during treatment with epidermal growth factor receptor inhibitors (EGFRI). Patients are hindered in their daily activities and cannot maintain privacy about their illness because of the prominent side effects. The aesthetic discomfort, which is frequently associated with itching or painful skin or nails can lead to a decreased health related quality of life (HRQoL) and to dose reduction or discontinuation of anticancer treatment. Patients with dermatological side effects have also an increased risk for cutaneous infections (at least 38%) which can complicate dermatological side effects.At present, evidence of the effectiveness of the management options for dermatological side effects is lacking, and the effect of the dermatological side effects on HRQoL and adherence remains poorly understood.Dexpanthenol cream (Bepanthen®, Bayer) has been used extensively to ameliorate acute radiation induced skin toxicity, diaper dermatitis, irritant hand dermatitis, graft-donor site wound healing and burn patients. We hypothesize that its skin healing possibilities decreases this kind of side effects.

Study objective

To assess the preemptive effect of Bepanthen® on decreasing the incidence of specific >= grade 2 dermatological side effects of interest in respect of compliance to EGFRI agents, HRQoL and the adherence during the 6-week skin treatment period. The adherence to the study creams will also be studied.

Study design

Multicenter, two-arm randomized, double blind, prospective parallel group design, phase III study

Intervention

80 patients will receive for the first 6 weeks of treatment Bepanthen crème, 80 patients Cetomacrogol crème to apply twice daily. Using FACT-EGFRI, a dermatology-specific questionnaire, this study examines the effect of these side effects on three domains of HRQoL - symptoms, emotions, and functioning. Severity of dermatological side effects will be assessed using the NCI-CTCAE v4.0. Correlation of dermatology HRQoL scores with NCI-CTCAE grade, sex, age,

type of EGFRI, and cancer type will be conducted.

Study burden and risks

The burden is to fill out 7 times a questionnaire (8-10 minutes each time) and depending of the local treatment guidelines 1 to 2 additional visits toe evaluate the skin condition.

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

* Male and female subjects
* >=18 years of age.

* Patients must have signed an approved informed consent form prior to registration on study.
* Histological proof of cancer.
* A planned course of EGFRI treatment for any type of cancer. Patients must be entered on study <= 7 days before EGFRI treatment begins. EGFRI treatments: (e.g. panitumumab, cetuximab, lapatinib, gefitinib, and erlotinib).
* Have an Eastern Co-operative Oncology Group (ECOG) performance status <= 2.
* Ability to complete questionnaire(s) by themselves or with assistance.
* Patients need to be free of infection and not using any topical treatments on the skin.

Exclusion criteria

Subjects meeting any of the following criteria will be excluded from the study:
* Use of other concurrent topical creams or lotions at baseline.
* Concomitant use of medications that may affect trial results (e.a. concurrent use of topical antibiotics, topical steroids, and other topical treatments on face and chest within 14 days of Day 0 (baseline); treatment with any systemic antibiotics within 7 days prior to Day 0.
* Active dermatological conditions other than papulopustular eruption that may affect trial results. A skin examination reveals the presence of another skin disease in face or chest that may obscure rash to EGFRI and/or condition (excessive facial hair, excessive scarring, sunburn, or other disfigurement) located on the skin that, in the study physician's opinion, would confound the evaluation of the papulopustular eruption.
* Known allergy or hypersensitivity to ingredients in Bepanthen® or Cetomacrogol.
* Known sensitivity, papulopustular eruption or other abnormal skin reaction to topical or systemic medications or cleansing products at baseline.
* Prior treatment with targeted therapy of any kind.
* Current use of agents that are known to be strong inducers or inhibitors of CYP3A4 that can not be stopped.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-09-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	02-08-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-12-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	ClinicalTrials.gov: Esperanz-001
CCMO	NL32146.094.10