Pilot study to determine the utility of a Likert-type scale to assess patients* experience of radiation dermatitis during radiotherapy for breast cancer.

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Objective: determine whether a Likert-type scale scoring system, specified for skin irritation reactions (erythema, itching, burning sensation of skin and general irritation of skin) can function as a tool to score the radiation-induced dermatitis...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries by physical agents
Study type	Observational non invasive

Summary

ID

NL-OMON36464

Source
ToetsingOnline

Brief title
N10RDA. Radiation dermatitis assessment

Condition

- Injuries by physical agents
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Radiation dermatitis, radiation induced skin reaction

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: geen financiering nodig

Intervention

Keyword: Evaluation, Likert-type score, Radiation dermatitis

Outcome measures

Primary outcome

1. Development of a tool to document patients* experience of the severity and duration of skin reactions after radiotherapy, using a Likert-type scoring system.

2. Determination of inter-patient variation, as a pilot to calculate the number of patients required for a comparative clinical study.

Secondary outcome

1. To assess if the Lickert-type score documented by the patient is comparable to the severity of the side effects evaluated by the investigator at the end of radiation therapy.

2. To assess any relationship to patient or treatment related factors to the recorded parameters of patient symptoms.

3. To obtain feedback from patients regarding the utility of topical symptomatic treatment of their radiation dermatitis

Study description

Background summary

Radiation skin toxicity is poorly documented and little is known about the

extent to which skin reactions cause distress or have impact on daily life. The management of radiation skin reactions is controversial, and often based on anecdotal evidence. Furthermore, it is known from previous trials that here is a large inter-patient variation in the degree of erythema developing as a result of radiotherapy to the chest wall in breast cancer patients. .

Study objective

Objective: determine whether a Likert-type scale scoring system, specified for skin irritation reactions (erythema, itching, burning sensation of skin and general irritation of skin) can function as a tool to score the radiation-induced dermatitis as experienced by patients whilst on radiotherapy for breast cancer. Further, to determine the inter-patient variation for the Likert-type parameter scores, to enable calculation of patient numbers required in a subsequent comparative trial. The influence of patient related and treatment related factors on the Likert-type scores will be evaluated.

Study design

This study is a single-center, open-label, non randomized prospective pilot study in patients with radiation-induced skin reactions during radiotherapy for breast cancer. Patients will be asked te fill in a questionnair (with a Likert-type scale) once a week during the radiotherapy and and at 4 weeks after finishing radiotherapy. The standard advice for the management of radiation-induced skin reactions of the NKI-AVL will be given for skin care during the radiation period.

Study burden and risks

The use of creams, and other topical treatments can be considered as supportive care for radiation dermatitis, intended to relieve symptoms of itching and irritation. The most important side effect associated with the use of creams is a contact dermatitis as a reaction to one of the components. This is rare and difficult to distinguish from radiation-induced dermatitis, unless it extends outside the radiation field.
This study will be carried out in a patient group treated for breast cancer. However, an effective symptomatic treatment for radiation dermatitis is also relevant for other radiation sites, especially with the increasing use of chemo-radiation, for example in the head and neck area, high dose lung cancer treatments, and pelvic malignancies.

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

Female patients undergoing external beam radiotherapy for breast cancer.
Total prescribed dose 40 Gy or more
Irradiation of one or more of the following target areas: breast, chest wall, regional lymph nodes.
Patient can apply creams
Patient able to understand and complete the questionnaire.
patiente is willing to sign informed consent

Exclusion criteria

Postoperative wound infection within treatment area;
Ulceration or open wound in treatment area;
History of skin diseases in the irradiated area;
Any clinical significant medical condition that could interfere with the conduct of the study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2011
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL31855.031.11