ISRCTN03885092 https://doi.org/10.1186/ISRCTN03885092

A randomised, double-blind controlled trial of mometosone furoate cream versus placebo to prevent radiation dermatitis of the breast and chest wall

Submission date
07/07/2010

Recruitment status
No longer recruiting

Registration date
07/07/2010

Overall study status
Completed

Last Edited
24/01/2022

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-effect-using-steroid-cream-decrease-skin-reactions-caused-having-radiotherapy

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-002352-15

Protocol serial number
2191

Study information

Scientific Title
A randomised, double-blind controlled trial of mometosone furoate cream versus placebo to prevent radiation dermatitis of the breast and chest wall

Acronym
Skin Study

Study objectives
A prospective, double blind, randomised study investigating the effect of mometasone furoate on the prevention of radiation dermatitis of the breast and chest wall. Scoring systems include visual scoring and reflectance spectrometry. Participants receiving a 40 Gy, 15 fractionated, 3 week radical course of whole breast radiotherapy plus or minus breast boost will be eligible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 06/Q0201/79)

Primary study design
Interventional

Study design
Single centre randomised interventional process of care trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
Placebo or mometasone furoate. Assessments are taken at baseline, day 8, 15, 21, 29, 36 and 43.

Study entry: single randomisation only

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Mometasone furoate

Primary outcome(s)
Change in visual skin assessment

Key secondary outcome(s)
1. Objective skin assessment
2. Changes in quality of life measures

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or over, either sex
2. Receiving 40 Gy 15 fractionated, 3 week radical radiotherapy to the breast or chest wall
3. Patient provides informed consent to participate in the study and completes follow up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Skin involvement of disease
2. Untreated bacterial, fungal or viral skin lesions
3. Inability to self administer creams

Date of first enrolment
02/11/2009

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Rosemere Cancer Centre
Preston
United Kingdom
PR2 9HT

Sponsor information

Organisation
Lancashire Teaching Hospitals NHS Trust (UK)

ROR
https://ror.org/02j7n9748

Funder(s)

Funder type
Charity

Funder Name
Rosemere Cancer Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/11/2014	24/01/2022	Yes	No
Plain English results			24/01/2022	No	Yes