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

EudraCT/CTIS number
2006-002352-15

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Single centre randomised interventional process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 measure
Change in visual skin assessment

Secondary outcome measures
1. Objective skin assessment
2. Changes in quality of life measures

Overall study start date
02/11/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 120; UK sample size: 120

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
England

United Kingdom

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

Sponsor information

Organisation
Lancashire Teaching Hospitals NHS Trust (UK)

Sponsor details
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
England
United Kingdom
PR2 9HT

Sponsor type
Hospital/treatment centre

Website
http://www.lancsteachinghospitals.nhs.uk/

ROR
https://ror.org/02j7n9748

Funder(s)

Funder type
Charity

Funder Name
Rosemere Cancer Foundation (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results			24/01/2022	No	Yes
Results article		15/11/2014	24/01/2022	Yes	No