ISRCTN28188789 https://doi.org/10.1186/ISRCTN28188789

Efficacy of a new Vitamin E foam in prevention of early skin damage in patients undergoing radiotherapy

Submission date	Recruitment status	[ ] Prospectively registered
08/11/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/11/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/11/2005	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Massimo Milani

Contact details
Via A. Nota 18
Milan
Italy
20126
+39 (0)253548007
massimo.milani@mipharm.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VEF03/04

Study information

Scientific Title

Acronym
VEFOAM

Study objectives
To evaluate if a new topical formulation of Vitamin E is efficacious in the prevention of early skin damage during radiotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB approved study protocol in April 2004

Study design
Randomised parallel group Investigator blinded

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Skin damage after radiotherapy

Interventions
Vitamin E foam topical application versus emollient standard cream

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin E foam

Primary outcome measure
1. Radiation Therapy Oncology Group (RTOG) skin score
2. Skin damage score

Secondary outcome measures
Tolerability

Overall study start date
01/03/2004

Completion date
01/06/2005

Eligibility

Key inclusion criteria
Patients undergoing radiotherapy for breast or thoracic cancer

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
80

Key exclusion criteria
Known sensibility to topical Vitamin E

Date of first enrolment
01/03/2004

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
Italy

Study participating centre

Via A. Nota 18
Milan
Italy
20126

Sponsor information

Organisation
Mipharm (Italy)

Sponsor details
Via B. Quaranta 12
Milan
Italy
20126
+39 (0)253548007
massimo.milani@mipharm.it

Sponsor type
Industry

ROR
https://ror.org/0441v1872

Funder(s)

Funder type
Industry

Funder Name
Mipharm SPA

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration