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

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Additional identifiers

Protocol serial number 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

Study type(s)

Prevention

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(s)

- 1. Radiation Therapy Oncology Group (RTOG) skin score
- 2. Skin damage score

Key secondary outcome(s))

Tolerability

Completion date

01/06/2005

Eligibility

Key inclusion criteria

Patients undergoing radiotherapy for breast or thoracic cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

https://ror.org/0441v1872

Funder(s)

Funder type Industry

Funder Name Mipharm SPA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration