

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

<b>Submission date</b> 08/11/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/11/2005	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**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**

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## **Sponsor information**

### **Organisation**

Mipharm (Italy)

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### **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