Vitamins also healthy after therapeutical radiation?
Investigation after the effects of l-ascorbid acid and d-a-tocopherol

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The most important objective from this investigation is to prevent or substitute the damage which is coused by therapeutical radiation. As it's most likely that the skin damage as a result of therapeutical radiation can be more limited. From...

Ethical review	Not approved
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON34247

Source
ToetsingOnline

Brief title
Vitamins also healthy after therapeutical radiation?

Condition

- Epidermal and dermal conditions

Synonym
Erytheem, Roodheid

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: De maatschap radiologie betaald de huur van de photospectrometer.

Intervention

Keyword: erythema, l-ascorbid acid and d-a-tocopherol, Radiation, skin

Outcome measures

Primary outcome

Group sample sizes of 15 in both groups to achieve 93% power to detect a

difference of 10,0 between the null hypothesis that both group means are 45,0

and the alternative hypothesis that the mean of group 2 is 35,0 with estimated

group standard deviations of 8,0 and 8,0 and with a significance level (alpha)

of 0,05 using a two-sided two-sample t-test.

Secondary outcome

nvt

Study description

Background summary

Making a start with the development of a scientific guidline for the treament of the skin after therapeutical radiation

Study objective

The most important objective from this investigation is to prevent or substitute the damage which is coused by therapeutical radiation. As it's most likely that the skin damage as a result of therapeutical radiation can be more limited.
From former studies is shown that the effects of l-ascorbic acid and d-α-tocopherol are exceptional in comparing to other products. Recently there has been a literary studie where former studies haven been put together, this is shown in addendement C from the protocol.
l-Ascorbic acid and d-α-tocopherol are able to reduce free radicals, whereby the skin is able to recoverand to protect itself.

The investigations after the effects of l-ascorbic acid and d-α-tocopherol are tested, only after ultraviolet radiation. Thereby is there in this investigation searched if both ultraviolet as ionizing radiation cause similar damage, there has been found clear similarities.

Study design

A pilotstudy where the choise has been made to treat half of the patients with and the other half without the use of the serum

Intervention

Daily topical apply of a serum containing 15% l-ascorbic acid, 1% d-α-tocopherol and 0,1% ferulic acid

Study burden and risks

The patients will be minimal loaded as the measurments will be directly after their therapeutical radiation. Where will als be the oppurtunity to fill in the questionarys.
At home the patients will be applying the serum topical at the breast. This will only take seconds.
Futher there is no load and the risks are very low, there can only be developed a hypersensitivity for one of the ingredients and in the most unlikely case the treatment will be less effective.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Woman diagnosed with breastcancer which have undergone breast saving therapie
2.Radiation according to the "new" method from 21 treatments.
3.WHO-performace status 0-2
4.Skintyp according to Fitzgerald 1-4
5.Gave their permission

Exclusion criteria

1.Patientgroup shouldn't be treated or being treated with chemotherapy
2.No radiotherpy in the past
3.No hypertrofia / keloidal scarring
4.No metastases
5.No diabetes mellitus type 1&2
6.No illness which can influence the skinrecovery
7.No medication which couse hypersensibility from the skin
8.No hypersensitivity for one of the ingredients

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	C E Ferulic
Generic name:	C E Ferulic
Registration:	Yes - NL outside intended use

Ethics review

Not approved

Date:	01-10-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-020864-39-NL
CCMO	NL33434.044.10
Other	Volgt z.s.m.