Treatment of Actinic keratosis: topical ingenol mebutate versus 5%5-fluorouracil versus 5% imiquimod versus photodynamic therapy.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22756

Source
Nationaal Trial Register

Brief title
AKTI-trial

Health condition

Actinic keratosis

Sponsors and support

Primary sponsor: K. Mosterd, dermatologist
Maastricht University Medical Center
Source(s) of monetary or material Support: ZonMw, goed gebruik geneesmiddelen

Intervention

Outcome measures

Primary outcome

Primary outcome measure: treatment success (i.e. the proportion of patients with >75% lesion reduction in the number of AK lesions counted at baseline in the treatment area) 12 months post treatment.

Secondary outcome

- Partial response (proportion of participants at 12 months post treatment with 50-75% reduction in number of AK lesions)

- Treatment failure (proportion of participants at 12 months post treatment with <50% reduction in number of AK lesions)

- Complete lesion clearance (proportion of lesions with 100% clearance in all treated patients per study arm)

- Partial lesion clearance (proportion of lesions with >75% clearance in all treated patients per study arm)

- Decrease in number AK from baseline per patient

- Number of SCC¡¯s developing in the treatment area

- Healthcare/treatment costs

- Side effects

- Patient satisfaction

- Cosmetic outcome

- Treatment compliance

Study description

Background summary

Rationale: Skin cancer is the most common cancer in Caucasians and therefore a major public health issue. Its incidence is increasing rapidly. Actinic keratosis (AK) is the most prevalent precancerous chronic skin condition. It can transform into squamous cell carcinoma (SCC). AK¡¯s generally arise in a skin area that has diffuse precancerous damage, a phenomenon called field cancerization. Because of its precancerous character, it is advised to treat AK and herewith prevent development into SCC. The most frequently used field-directed treatments in the Netherlands are photodynamic therapy (PDT), topical 5% f-fluorouracil (5% 5-FU) and topical 5% Imiquimod (5% IMI). Lately another topical product is approved by

Dutch healthcare insurances: Ingenol mebutate (IM). Up to date, which treatment the patient will receive, does not rely on evidence-based-medicine, but generally on the preference of the physician. Current national and international guidelines state no clear recommendations for the best choice of therapy. The aim of this study is to investigate what is the most effective field-directed treatment for AK.
Objective: Determine which treatment is the most effective treatment in terms of lesion reduction, costs and patient satisfaction when comparing topical treatment with photodynamic therapy (PDT), 5% 5-fluorouracil (5-FU) cream, 5% Imiquimod (IMI) cream and 0.015%ingenol mebutate (IM) gel, in treatment of actinic keratosis (AK)
Study design: Prospective randomized controlled multi-centre study.
Study population: Patients, >18 years, Fitzpatrick skintype I-IV, with an area of minimal 25cm2 and maximal 100 cm2 AK, Olsen grade I-III, localized in the head,- and neck area, visiting Dermatology departments of the Maastricht University Medical Centre (MUMC), Catharina hospital Eindhoven, Atrium Medical Centre Heerlen or VieCuri Medical Centre Venlo.
Intervention: PDT versus 5% 5-FU versus 5% IMI versus 0.015% IM.
Main study parameters/endpoints: Primary outcome measure is adequate treatment success, defined as the proportion of participants at 12 months post treatment, with ¡Ý 75% reduction in the number of AK lesions counted at baseline in the treatment area. Secondary outcomes: partial response (proportion of participants with 50-75% reduction in number of AK lesions after 12 months compared to baseline), treatment failure (proportion of participants with <50% reduction in number of AK lesions after 12 months compared to baseline), partial lesion clearance (proportion of lesions with ¡Ý75% clearance), complete lesion clearance (proportion of lesions with 100% clearance in all treated patients), decrease in number AK from baseline per patient, costs, side effects, patient satisfaction, cosmetic outcome and treatment compliance, proportion of patients who develop SCC in treated areas.

Study objective

Primary outcome is to define the treatment success of four topical treatment modalities for AK. We expect topical 5-flourouracil to be the most cost-effective treatment.

Study design

3 and 12 months follow-up time

Intervention

Ingenol mebutate versus 5% 5-fluorouracil versus 5% imiquimod versus photodynamic therapy

Contacts

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Eligibility criteria

Inclusion criteria

- Patients older than 18 years

- Female in child bearing potential should be using contraceptive measures, during and till 3 months post-treatment

- Fitzpatrick skintype I-IV

- Clinically confirmed diagnosis of AK

- One joint area of minimal 25 cm2 and maximal 100 cm2 of AK

- AK Olsen grade I-III

- Location: head/neck area

Exclusion criteria

- Received any kind of treatment for AK in the past 3 months

- (N)MSC in target area

- Immuno-comprised status

- Use of immunosuppressant drugs in the past 3 months and / or at time of treatment (inhalation corticosteroids / nasal corticosteroids are permitted)

- Porphyria

- Not able to give informed consent

- Allergy to study drugs or nut/soy products

- Pregnant and breastfeeding women

- Genetic skin cancer disorders

- No understanding of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	624
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 50427
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4595
NTR-old	NTR4849
CCMO	NL50621.068.14
OMON	NL-OMON50427

Study results