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

Gepubliceerd: 14-10-2014 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22756

Bron
Nationaal Trial Register

Verkorte titel
AKTI-trial

Aandoening

Actinic keratosis

Ondersteuning

Primaire sponsor: K. Mosterd, dermatologist
Maastricht University Medical Center
Overige ondersteuning: ZonMw, goed gebruik geneesmiddelen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

3 and 12 months follow-up time

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	624
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50427
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten