Diagnose van basaalcelcarcinoom in het hoofd-hals gebied door dermatoscopie en reflectie confocale microscopie.

Gepubliceerd: 18-01-2017 Laatst bijgewerkt: 24-03-2024

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	Huidneoplasmata maligne en niet-gespecificeerd
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27500

Bron
Nationaal Trial Register

Verkorte titel
BCC-COMI

Aandoening

- Huidneoplasmata maligne en niet-gespecificeerd

Aandoening

basal cell carcinoma, diagnostics, dermoscopy, confocal microscopy, rcm

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Netherlands Cancer Institute
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

- Medische hulpmiddelen

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

1. The diagnostic accuracy of dermoscopy and HH-RCM in diagnosing and subtyping (Table 1) of BCC in the head and neck, compared to the current diagnostic reference standard (3mm punch biopsy).
2. Rate of over- and understaging of BCC subtypes in the head and neck by dermoscopy (index), HH-RCM (index), and punch biopsy (control) compared to the outcome of the final excisional specimen (reference standard).

Secundaire uitkomstmaten

1. Reliability of naked-eye examination in the diagnosing and subtyping of BCC in the head and neck.
2. Diagnostic value of established dermoscopic and RCM criteria in the differentiation of BCC subtypes in the head and neck.
3. Inter- and intraobserver agreement of the dermoscopic and HH-RCM criteria, diagnosis and subtyping of BCC.

Toelichting onderzoek

Onderzoeksopzet

Lesions with a negative BCC punch biopsy outcome will be re-evaluated at 6 months. All other research related data will be collected on the day of initial consultation or during standard of care.

Onderzoeksproduct en/of interventie

Consecutive patients with suspected BCC in the head and neck on naked-eye examination will be prospectively enrolled during regular consultation.

Study group procedures :
I. Standardized skin overview and macroscopic lesion photography by coordinating investigator.
II. Dermoscopic imaging by coordinating investigator.
III. HH-RCM assessment by coordinating investigator.

IV. 3mm punch biopsy by coordinating investigator
V. Punch biopsy specimen evaluation by a board-certified pathologist blinded to clinical/dermoscopic/HH-RCM outcomes.
a. BCC positive: to VI
b. BCC negative: 6 month follow-up to minimize chance of false negatives.
VI. Therapeutic excision with margin based on current Dutch BCC guidelines by a board-certified dermatologist or oncologic head and neck surgeon, followed by evaluation by a board-certified pathologist blinded to clinical/ dermoscopic/ HH-RCM/ punch biopsy outcomes.
In case Mohs surgery is indicated, tumor debulking will be performed during surgery for conventional histopathological analysis in addition to evaluation of the Mohs slides.
VII. Additional evaluation:
a. Expert evaluation of outcomes II and III blinded to the outcome of the diagnostic reference standard and excisional outcomes.
b. Blinded evaluation of the histopathologic outcomes by a second pathologist. In case of discordance this will be solved by discussion/third pathologist.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with suspected primary BCC on naked-eye examination as assessed by an experienced board-certified dermatologist.
2. Lesion localization in the head and neck (i.e. supraclavicular/above the 7th cervical vertebrae) with an indication for surgical treatment.
3. Anatomic localization of the lesion allows evaluation by HH-RCM and dermoscopy.
4. Patient age ¡Ý 18 years and is willing and able to comply with the study requirements and give written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Recurrent BCC, defined as a suspected BCC localized within 5mm from the site of previously surgically or non-surgically treated BCC.
2. Suspected BCC localized outside the head and neck (i.e. infraclavicular/below the 7th cervical vertebrae).
3. Anatomical localization of lesion not accessible by HH-RCM or dermoscopic imaging.
4. Patients with genetic syndromes with increased risk of developing BCCs (e.g. Gorlin-Goltz, xeroderma pigmentosa).
5. Patients being treated by immunosuppressive medication.
6. Lesions on previously radiated skin.
7. Patients not eligible for surgical excision due to co-morbidity/ patient refusal.

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Diagnostiek

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-04-2017
Aantal proefpersonen:	258
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	18-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6004
NTR-old	NTR6502
Ander register	Interne code : N17BCC

Resultaten