Dermatoscopy in general practice.

Gepubliceerd: 10-05-2010 Laatst bijgewerkt: 18-08-2022

We expect the dermatoscope to give an increase in diagnostic accuracy in general practice.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26705

Bron
Nationaal Trial Register

Verkorte titel
Optoderma

Aandoening

skin neoplasms
skin malignancies
skin cancer
melanoma
basal cell carcinoma
naevi
huidkanker
melanoom
basaalcelcarcinoom

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development. 6th round: 'Alledaagse Ziekten'
research subsidy: C. J. L Koelink (funded by SBOH)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the diagnostic accuracy of the dermatoscope as diagnostic test for the evaluation of skinlesions.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

GP's are regulary asked to analyse a pigmented lesion or local swelling (nodule) of the skin. It is expected that in the future there will be a increase of skincancer patients in The Netherlands and in other European countries because of increasing incidence and the aging of the population. In secundary care the dermatoscope offers an increase in specificity (15%) and sensitivity (25%) to the diagnostic proces and also gives a decrease of small surgery. We expect the dermatoscope to give an increase of diagnostic accuracy in the GP's office.

Objective of the study:

The primary aim of the study is the validation of the dermatoscope as a diagnostic aid for analyzing patients who visit the GP with the suspicion of a skin malignancy. Secundary aim of the study is the determination of the extent of health care consumption: the number of referrals to secundary care, the number of excisions send to the pathologist, both compared to the golden standard (clinical judgement of the dermatologist or the histological diagnosis). In a economical evaluation the costs of both diagnostic strategies will be investigated.

Study design:

The design of this study is a diagnostic trial. In which the GP's will be randomized in stead of patients.

Study population:

The source populations consists of patients aged 18 years or older, who visit the GP because of a skin lesion for which they have not consulted their GP before. Also the GP is uncertain of

a benign diagnosis.

Intervention:

In the intervention group the dermatoscope will be used after clinical analysis to analyse the skinlesion and to diagnose this lesion. In the control group the diagnostic fase will be finished after the clinical analysis without the use of a dermatoscope.

Outcome:

The primary outcome measure is the diagnostic accuracy of the dermatoscope as a diagnostic test analyzing skinmalignancies in general practice. Secondary outcome measures are the sensitivity, specificity, the number of excisions c.q. biopsies and referrals to secundary care. In a economical evaluation the costs of the two diagnostic strategies will be analysed.

Doel van het onderzoek

We expect the dermatoscope to give an increase in diagnostic accuracy in general practice.

Onderzoeksopzet

Patients will be included for 1 year.

Onderzoeksproduct en/of interventie

In the interventrion group the dermatoscope will be used after normal clinical evaluation in order to diagnose and evaluate the lesion. In the controlgroup the evaluation of the skin lesion ends after normal clinical evaluation, without the use of the dermatoscope.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are eligible for the study if they are 18 years of age or older, if they have a suspected skinlesion and if they have given informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients will be excluded if they already had a treatment for a skin malignancy, if they have a serious disease or if they cannot be asked to participate in this research (to the opinion of the general practitioner).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	476
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-05-2010
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	NL2195
NTR-old	NTR2319
Ander register	ZonMW : 80-81000-98-117
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A