Optimalisation of the diagnosis of patients with skin malignancies in general practice by using the dermatoscope.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON39098

Source
ToetsingOnline

Brief title
Dermatoscopy in general practice.

Condition

- Skin neoplasms malignant and unspecified

Synonym
skin cancer, skin neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZonMw;6e ronde Alledaagse Ziekten,onderzoekssubsidie mw. drs. CJL Koelink (verleend door de SBOH)

Intervention

Keyword: dermatoscopy, diagnostic accuracy, growing incidence, skin neoplasms

Outcome measures

Primary outcome

The primary outcome measure is the diagnostic accuracy of the dermatoscope as a diagnostic test analyzing skinmalignancies in general practice.

Secondary outcome

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.

Study description

Background summary

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.

Study objective

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.
Secondary aims of the study are 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.
The diagnostic accuracy of the dermoscope for pigmented and non-pigmented skin lesions.

Study design

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

Intervention

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

Study burden and risks

The use of the dermatoscope in the interventiongroup will not give any physical burden to the patient, as the investigation is non-invasive. The dermatoscope is already a accepted diagnostic tool in secundary care.
GP's in both groups will get a diagnostic training to optimalize the diagnosis of patients with skin malignancies, which will be in favour of the patients.
The golden standard for the diagnosis is the judgement of the dermatologist (based on teledermatology / teledermatoscopy or after referral) or in case of excision / biopsy the diagnosis of the pathologist. In case the lesion cannot be judged by teledermatology / teledermatoscopy the patient shall be refered to a dermatologist. The number of excisions / biopsies is expected to stay the same in both groups or to decrease by optimalization of the clinical judgement.
Because of this research, the appointment will take more time than normal, although it can be done in 1 appointment en the patient won't have to come back because of this research.

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

patients are eligible for the study if they are >= 18 years of age, if they have a suspected skinlesion and if they have given informed consent.

Exclusion criteria

Patients will be excluded if they already get 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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2010
Enrollment:	476
Type:	Actual

Medical products/devices used

Generic name:	dermatoscope (Dermlite)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-04-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL30571.042.09