SKINCATCH Trial: Skin cancer and tumor health care

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The objective of this study is to improve skin cancer care in primary health care and provide a scientific basis for implementing guidelines regarding care of low risk skin cancers. In order to be able to shift curative oncological care from...

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

Summary

ID

NL-OMON42459

Source
ToetsingOnline

Brief title
SKINCATCH Trial

Condition

- Skin neoplasms malignant and unspecified

Synonym
basal cell carcinoma, skin cancer, skin malignancies

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Achmea Gezondheidszorg

Intervention

Keyword: basal cell carcinoma, excisions, skincancer, skintumor

Outcome measures

Primary outcome

Primary outcomes

1. therapeutic: proportion of histological complete excisions of BCCs by GPs:

low risk BCCs, i.e. smaller than 1 cm, not on high-risk locations on the body,

superficial spreading or nodular histological subtype; compared to the

proportion of the histological complete excisions of these same type of BCCs by

dermatologists in the care-as-usual arm.

Secondary outcome

Secondary outcome

Diagnostic: positive predictive value of the diagnosis of the skin tumor by the

GP in the intervention arm compared to the GP in the care-as-usual arm.

Cost-effectiveness analysis of the direct costs of the intervention.

Patient preferences and patient satisfaction.

Study description

Background summary

The Erasmus MC Dermatology research group has shown that the incidence of skin cancer is rising steeply during last years.
In absolute numbers this is a large group of patients. The approach in care in skin cancer hasn't adapted to these high number of patients in the Netherlands. There are no clear rules or guidelines in skin cancer care for primary health care, to secondary and tertiary.

Skin cancer care is about diagnostics, treatment, referral and follow up.
In primary health care there is lack of training, guidelines and expertise.
Regarding the size and the large growth number of skin cancer patients, there is an urgent need for a new concept of care. Above that, there are no regulations in secondary care on which specialty is the main responsible one for skin cancer and skin cancer related diseases.

Facts and figures:
ca. 70.000 new cases of skin cancer per year in The Netherlands
this numbers keeps rising with more than 5% per year. In ten years these numbers are estimated to be 109.000.
Most of these tumors are low risk skin cancers, mainly basal cell carcinoma (BCC).
ca. 40% of all financial claims by dermatologists are regardings skin tumors: a disproportional burden on the dermatological knowledge and science.
ca. 14% of all malignancies are skin cancer in The Netherlands, that makes skin cancer the second most common type of cancer in The Netherlands: this is without the numbers of BCC. BCC is such a common type of cancer, the cancer registration doesn't count the number of cases, due to the lare number. Would BCC be taken into account, skin cancer is very likely to be the most common type of cancer in The Netherlands.
For example: 1 out of the 5 Dutch gets skin cancer in their lifetime.

Current situation on skin cancer care in The Netherlands:
In the recent years the role of the general practitioner (GP) in cancer care has shifted from palliative care to follow-up.
There are no guidelines concerning skin tumors for the GP (so called 'NHG-standaarden'), let alone guidelines with a scientific base.

This results in a great variance in care in practices:

A part of the GPs excises skin tumors themselves (not always with histopathological examination). These tumors are also high risk tumors, that could better be treated in secondary health care. High risk tumors are tumors that could metastasize, or located on a high risk location on the body, or of a risky size.

A part of the GPs refers all skin tumors to the dermatologist. These tumors are also low risk tumors, which causes a burden on specialist care in secondary health care and leads to costs that could be prevented. Low risk tumors, are benign tumors, rarely metastasizing tumors, small sized and not on a high risk location on the body.

The principle of equality in care possibilities for every similar patient, is violated with this, as for a patient it matters to which GP he will go and successively which treatment options he will get. The approach is random.

GPs lack the possibility of neccessary training in skincancer. The resident education of the GPSs is mainly based on experience in practice concerning skin cancer. Skin cancer is the most common type of cancer and the GPs has a portal function in care and an important function in the approach.

Small surgical operations can get reimbursed in the GP practice, without scientific research that quality of care is maintained, moreover without any guidelines or work agreements with secondary health care.

Renovation of infrastructures of cancer care:
By training the GP, the position of the primary care strengthens and the infrastructure of cancer care
will be more efficient and clear for both the professional and the patient. The GP will play a curative role in
the treatment of low-risk skin tumors, if provided proper knowledge and expertise and integrated care in
skin cancer. The training focuses on making a distinction between a low and a high risk skin tumor and
excision of low risk skin tumors .

Results of renewal of the infrastructure:
»Drop in unnecessary referrals to secondary care (eg. benign tumors) by better diagnosis
in primary care.
»Substitution of care from the secondary to primary health care, aslow-risk tumors stay in primary health care.
»Improving quality of care and improving patient safety by better recognition of high
risk tumors, which should be referred to secondary care.

Current isse:
Current health care in skin cancer is not ready for the large increase in the number of skin cancer patients in the coming years.
The problems that now exist ((unjustified referrals, unjustified non-referrals and low expertise among general practitioners) will increase with the increasing number of patients if nothing is done about it. This has qualitative, financial and social undesirable effects.

Research plan:
Randomized controlled trial (RCT) in which general practitioners are trained by dermatologists in the
diagnosis and excision of skin tumors. The hypothesis is that after training GPs are not qualitatively
inferior to the dermatologists with respect to the excision of low-risk skin tumors.
The aim is providing a scientific foundation to shift care for low risk skin

tumors from secondary to primary health care.

Concepts:
low risk skin tumors are tumors that are benign, or those who rarely metastasize (certain types of BCC) and are not located on a high risk location on the body and do not have a large size. High risk skin tumors are tumors that are malignant, with greater risk of metastases, or located on a high risk location on the body or of a large size.

Study objective

The objective of this study is to improve skin cancer care in primary health care and provide a scientific basis for implementing guidelines regarding care of low risk skin cancers.
In order to be able to shift curative oncological care from secondary to primary health care high level of evidence is needed in the form of a randomized controlled trial (RCT). In this way, the chance of success of changing care in general practice and the dermatology practice is higher.
The objective is to conduct a randomized controlled trial, in which GPs are trained by dermatologists in diagnosing and treating skin tumors. The successrate of the skin cancer excisions by the GPs is compared to the successrate in usual care, the dermatologists. Non-inferiority in this case is that GPs will not perform worse than dermatologists in excising low risk skin cancer, measured in histological completeness. If indeed there is no loss of quality of care, there are clear indentifiable additional benefits for the patients involved if treated by the GP: lower costs, familiarity with the GP, practical issues as time and distance, and continuity of doctor-patient care. Form a social perspective, the benefits for health care are increasing the expertise of general practitioners in skin cancer and improving skin cancer care. So that every patients gets the same treatment options, without this being dependant on the provider of care.

Study design

Multicenter cluster randomized non-inferiority trial with two parallel arms in open setting.

Multicenter: Erasmus MC is the initiator. The GP practices that are included are all over the west of The Netherlands,
The clusters are the general practitioner practices (1 or more GPs).

GP are randomized in two groups, the intervention group and the care-as-usual group, the two parallel arms..
A patient that presents themselves to the GP with a skin tumor at a GP in one of these arms, will be asked to participate in the study.
To eliminate spill-over effect, GPs in group practices will be in one of these

arms only.

Non-inferiority: it is stated that the GPs in the intervetion arm perform not more than 5% worse in terms of histological clearance of the basal cell carcinoma compared to the care-as-usual, the dermatologists.

Open setting: as the intervention is education and surgery blinding is not possible for the GP or the patient.

Intervention

Intervention regarding the patients

Eligible patients with a skin tumor may be subjected to the following interventions:
1. a skin biopsy
2. skin cancer excision by the GP

Intervention regarding the GPs

The GPs in the intervention arm receive the following intervention:
1. theoretical and practical training in skin cancer, aimed at the diagnosis of skin tumors and treatment of basal cell carcinomas.
2. continuous e-learing about skin tumors
3. direct phone and email contact with the dermatology department of the Erasmus MC
4. part of the training is on site surgical training at the GP practice.

The GPs in the care-as-usual arm will treat patients as usual.

Study burden and risks

The burden and the risk of participation is very minimal for the patients.

The burden on the patients consists of filling out three questionnaires, in a period of 6 months (t = 0, t =3 months, t = 6 months). The risk is very low. The risk is that the tumor is at first not completely excised by the GP, after which the patient will be referred to the dermatologist for further care. Five and ten years after treatment of the tumor the patient will be contacted (by phone or written) to assess what happened further to the tumor.

The burden for the GPs is very low and involves following the course and performing small surgical procedures. GPs that are inrolled in the study do so only after accepting these interventions.

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

patient presenting with a skin tumor at the general practitioner

Exclusion criteria

age under 18
critically ill (ASA classification 3,4,5,6)
unable to understand patient information material without an interpreter or help

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2016
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	27-01-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	21-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52923.078.15