Surgical excision versus combined therapy with Curettage and Imiquimod for Nodular Basal Cell Carcinoma: an open, non-inferiority, randomized controlled trial

Published: 24-09-2014
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Primary objective: To compare long-term efficacy of curettage prior to IMQ 5% cream (Aldara®) therapy versus standard surgical excision in primary nBCC.Secondary objective: To assess compliance, pain, cosmetic outcomes, patient satisfaction, patient...

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

Summary

ID

NL-OMON44993

Source
ToetsingOnline

Brief title
S.C.I.N. Trial

Condition

- Skin neoplasms malignant and unspecified

Synonym
Nodular Basal Cell Carcinoma, Skincancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Meda Pharma BV

Intervention

Keyword: Basal Cell Carcinoma, Curettage, Imiquimod, Surgery

Outcome measures

Primary outcome

The primary study endpoint is the proportion free of initial nBCC patients at one 1 year after end of treatment (defined as absence of initial treatment failure or any clinical signs of subsequent local recurrence). In case there is clinical suspicion of BCC, a 3 mm punch biopsy will be taken for histological verification.

Secondary outcome

Secondary outcome parameters are the 5-year cumulative probability of recurrence free of initial nBCC survival at 5 years after end of treatment, compliance, cosmetic appearance, patient satisfaction, patient preference and cost-effectiveness.

Study description

Background summary

Basal cell carcinoma (BCC) is a slow-growing, locally invasive malignant epidermal skin tumour. It is the most common malignant disease in Caucasians, representing approximately 80% of all cases of skin cancer and is therefore an important health problem. In the Netherlands incidence rates are 165 for men and 157 for women per 100.000 person-years, and these rates are rising with 3-10% every year.
A simplified histological classification of BCCs includes the following three

subtypes: nodular, superficial and infiltrative variants, with the nodular variant being the most frequent type. Although a characteristic feature of BCCs is their low risk to metastasize, if untreated they may be locally invasive and may induce considerable functional and cosmetic morbidity.

The gold standard treatment of all histological BCC subtypes is surgical excision, but not all patients are eligible for surgery. Surgery may lead to significant morbidity, and in some cases, it may result in disfiguring scarring. For this reason and to reduce workload and costs in the healthcare system, there is a growing demand for alternative, non-invasive, treatments. An advantage of non-invasive treatment options is that they can be performed by other healthcare professionals, such as general practitioners, specialized nurses or professionals in elderly homes.

For treatment of superficial BCCs (sBCC) non-invasive treatments, such as topical imiquimod (IMQ), 5-fluorouracil (5-FU) or photodynamic therapy (PDT) are already commonly used. A recent study suggests that IMQ, besides being an immune-response modifier, can also directly inhibit sonic hedgehog (SHH) signalling, the most important pathway active in BCCs. This targeted effect of IMQ very likely explains the superior therapeutic effect compared to other non-invasive therapies. In literature, effective treatment of nodular BCC (nBCC) with IMQ has been described, however, efficacy was inferior to surgical excision. We hypothesize that the effectiveness of IMQ will rise by performing prior curettage to IMQ therapy.

Study objective

Primary objective: To compare long-term efficacy of curettage prior to IMQ 5% cream (Aldara®) therapy versus standard surgical excision in primary nBCC.

Secondary objective: To assess compliance, pain, cosmetic outcomes, patient satisfaction, patient preference and cost-effectiveness.

Study design

Open-label, parallel-group, non-inferiority, randomized controlled trial

Intervention

Studyarm 1: IMQ 5% cream once daily, 5 days a week, for six weeks, with prior curettage.
Studyarm 2: Standard surgical excision with 3-5 mm margins.

Study burden and risks

First visit, description of the lesion, biopsy , telephonic consultation,

surgical excision and two to three control visits are part of regular care of nBCC. Treatment with IMQ 5% cream and one control (after 5 year follow-up) visit are part of the study.
A potential risk when participating in this study is an allergic skin reaction for one of the components of the IMQ 5% cream.
Local skin reactions at application site represent a special safety issue for topically applied treatments. Local skin reactions can be easily controlled and therefore are acceptable for the subjects. In case of residu, an surgical excision has to be performed. We do not expect any other risks.

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

- Adults aged 18 years or older

- Primary histologically proven nodular basal cell carcinoma * 4mm and * 20mm in diameter
- Patient is able to apply cream
- Comorbidities may not interfere with study treatment (evaluated by investigator)
- Capable to understand instructions

Exclusion criteria

- A nodular BCC located in the H-zone of the face or hairy scalp
- Recurrent (previously treated) nBCC
- Aggressive histopathologcial BCC subtypes
- Life expectancy of less than five years
- Breast-feeding or pregnant women
- Serious comorbidities (evaluated by investigator)
- Use of immunosuppressive medication during the trial period untill 3 months after end of treatment or within 30 days before enrolment
- Patients with genetic skin cancer disorders

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2016
Enrollment:	144
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aldara 5% cream
Generic name:	Imiquimod 5% cream
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-09-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-11-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-04-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-09-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-12-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-01-2016
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2014-003479-52-NL
ClinicalTrials.gov	NCT02242929
CCMO	NL50433.068.14