Dermatoscopy versus loupe magnification for determination of surgical margins during Modified Mohs*surgery of facial basal cell carcinoma

Published: 15-03-2017
Last updated: 13-04-2024

The aim of this study is to evaluate the proportion of patients with a radical excision after the first excision using the dermatoscope for evaluating the peripheral borders compared to loupe magnification.Secondary parameters will be the influence...

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

Summary

ID

NL-OMON45661

Source
ToetsingOnline

Brief title
Dermatoscopy versus loupe magnification during Modified Mohs*surgery

Condition

- Skin neoplasms malignant and unspecified

Synonym
basal cell carcinoma, basalioma, skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Basal cell carcinoma, Dermascopy, Loupe magnification, Randomized trial

Outcome measures

Primary outcome

Proportion of one stage radical excisions

Secondary outcome

Secondary objectives are to study:

- the exact histologic margin, in millimetres, after final radical excision of

the specimen in the intervention group and the control group.

- the size of the defect, in millimetres, after excision in the intervention

group and the control group.

- the amount of re-excisions necessary to obtain surgical margins free of

tumour cells in the intervention group and the control group.

- duration of total procedure, in minutes, until reconstruction in the

intervention group and the control group

- total procedure time and medical costs for the intervention group and the

control group

- scar quality measured with the Patient and Observer Scar Assessment Scale

(POSAS)20 after 6 weeks and 12 months

- complications during the first 6 weeks after surgery such as infection,

bleeding, wound dehiscence in both groups

- sub-analysis of first time radical excision between both groups in the

different histological types of facial basal cell carcinoma

Study description

Background summary

Basal cell carcinoma (BCC) is the most commonly diagnosed skin cancer. It is known that BCC is a locally invasive malignant skin tumour with a high local tissue morbidity due to infiltration and destruction of adjacent tissues. Incidence rates vary from 788:100.000 people annually in Australia to 146:100.000 people annually in the United States. Despite the high incidence, metastasis of this tumour is rare. Estimates of metastasis incidence vary widely, ranging from 0.0028% to 0.55% of all BCCs.
The choice of treatment depends on multiple factors: tumour type, biological behaviour, size, location, physical condition and preference of the patient, local expertise and costs. Surgical excision with conventional margins is the most common and effective treatment. The goal of treatment is complete and radical removal of the tumour cells without loss of healthy tissue and with a low recurrence rate. The Dutch Guideline on BCC*s recommends conventional surgical excision with a clinical margin of 3 mm for a BCC * 10mm. For larger tumours and/or infiltrative BCC or for a recurrent BCC a margin of 5 mm is recommended. Visual magnifying tools for determination of the surgical margin are not discussed in the guideline.

After surgical excision, the margins of the BCC is examined for the presence of tumour cells. The gold standard for examination is using formalin-fixed paraffin embedded (FFPE) coupes. The definitive outcome of this FFPE procedure is known a few days after surgery. In case of incomplete excision a re-excision is then necessary and unfortunately, the reconstruction necessary to close the defect after the first excision has to be destructed. To prevent this situation the margins can be examined intraoperative. Two effective techniques for intra-operative margin control are Mohs* micrographic surgery (MMS) and frozen section controlled excision. The Medical Centre Leeuwarden, the Netherlands, performs Modified Mohs* surgery, or *bread loaf* frozen section controlled excision technique. Modified Mohs* is used in our centre when a BCC has an infiltrative character or when a primary reconstruction with a transposition- or rotationflap is needed.

Different studies describe high percentages (16-65%) of irradical excisions in patients with a facial BCC.These result underline the need for improvement to obtain a higher percentage of one stage radical excisions. A possible solution might be precise definition of the surgical margins of the BCC with a

magnifying device, such as a dermatoscope. Multiple studies have evaluated the use of a dermatoscope for determination of the surgical margins. Caresane et al. described a 98.5% direct radical excision in 200 patients with a facial BCC. Surgical margins were detected with visual inspection and checked with a dermatoscope and excision margins of 2mm were used. In 14 (7%) cases the lesion appeared larger than when evaluated clinically. Although this in not a (randomised) controlled trial it points out the possible advantage of the dermatoscope. In the prospective, non-randomised study of Carducci et al., in 112 patients with a facial BCC the surgical margin of 3 mm was determined using a dermatoscope and showed in 93% optimal direct radical excisions compared to 78% when using visual inspection (p<0,026) There are also studies in which no advantage of the use of the dermatoscope has been found. Four studies investigated MMS versus MMS in combination with dermatoscopy for determination of the surgical margins. None of these studies found significant differences in the amount of MMS stages between treatment groups. The biggest limitation off these studies is the sample size, the largest group contained 23 patients.In conclusion, we do not know yet whether the use of a dermatoscope will improve one stage radical excision in facial BCC*s.

The aim of our study is to compare the use of the dermatoscope to loupe magnification for determination surgical margins of facial BCC*s within a randomised controlled trial.

Study objective

The aim of this study is to evaluate the proportion of patients with a radical excision after the first excision using the dermatoscope for evaluating the peripheral borders compared to loupe magnification.
Secondary parameters will be the influence of the dermatoscoop on total time and costs of the procedure, scar quality (POSAS) and postoperative complications (bleeding, infection, wound dehiscence). Also the histological types of BCC and exact histological margin will be documented en evaluated.

Study design

Aims:
Does the use of a dermatoscope for determination of surgical margins in patients with facial BCC increase the percentage of one stage radical excisions compared to determination of the surgical margins using loupe magnification

Method
The intervention group wil contain patients with facial BCC treated with modified Mohs* using dermatoscopy for demarcation of surgical margins, versus the control group patients with facial BCC treated with modified Mohs* using loupe magnification for demarcation of surgical margins

Design
Randomised controlled trial

Hypothesis:
The use of dermatoscopy for demarcation of surgical margins will increase the proportion of one stage radical excisions.

Randomisation
Patients are randomly allocated to the group *dermatoscopy for determination of surgical margins* or *control group (loupe magnification for determination of surgical margins*. A randomisation list is prepared, using a random number table. The allocation sequence is concealed by using sequentially numbered, opaque sealed envelopes (SNOSE) prepared by the coordinating researcher which are opened at day of surgery after having obtained informed consent

Sample size:
In order to achieve at least 80% power to detect a difference between the group proportions of 15% (78% under the null hypothesis and 93% under the alternative hypothesis), a sample size of 2x94 patients is required. The test statistic used is the two-sided Fisher's Exact test . The significance level of the test was targeted at 0.05

Intervention

In the control group loupe magnification will be used for evaluation of the margins. In the intervention group the dermatoscope is used for evaluation of the margins .

Study burden and risks

No clear risks are described with the use of a dermatoscope. The extra information about the study at the first consult will approximately take a few minutes. Since we expect a higher percentage of one stage radical excisions the procedure might take less time.

Contacts

Public
Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8901 BR
NL
Scientific

Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8901 BR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Facial basal cell carcinoma which require reconstructive surgery

Exclusion criteria

<18 years
Recurrent basal cell carcinoma
Radiotherapy
Lesion larger than 2.5 cm (frozen section procedure not possible)
Basal cell carcinoma at the medial canthus (not accessible for dermatoscopic inspection)
Multiple basal cell carcinoma's per procedure
Patients unable to give informed consent (cognitive dysfunction, poor Dutch proficiency)

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2017
Enrollment:	188
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2017
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL59246.099.17