Treatment of large nodular facial BCC with imiquimod 5% cream before Mohs micrographic surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23593

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Basal cell carcinoma;

2. Mohs micrographic surgery;

3. imiquimod.

Sponsors and support

Primary sponsor: Drs S van der Geer.
No sponsors.
Source(s) of monetary or material Support: scientific fund of the Catharina Hospital Eindhoven

Intervention

Outcome measures

Primary outcome

Defect size after Mohs micrographic surgery.

Secondary outcome

1. Reduction tumour size after using imiquimod 5%cream;

2. Tumour size before Mohs micrographic surgery;

3. Reconstruction time;

4. Cosmetic outcome;

5. Costs;

6. Quality of Life;

7. Recurrence rates;

8. Histologic results, apoptosis.

Study description

Background summary

Imiquimod is effective for small superficial and nodular BCCs, total or partial clearance is obtained. Imiquimod could decrease tumour size before Mohs micrographic surgery and thereby defect size afterwards, this could improve cosmetic outcome.

Study objective

Pretreatment with imiquimod 5% cream will decrease the defect after Mohs micrographic surgery by decreasing the size of the basal cell carcinoma. And will thereby improve cosmetic outcome.

Study design

October 2007-March 2008 recruitment of patients;

November 2007-June 2008 treatment of patients;

January 2008-November 2009 Follow-up.

Intervention

40 patients receive Mohs micrographic surgery with a pretreatment with imiquimod (once daily, 5 days a week, 4 weeks)
40 patients will only undergo Mohs surgery.

Contacts

Public
Catharina Hospital Eindhoven, department of dermatology
Michelangelolaan 2

S Geer van der
Eindhoven 5602 ZA
The Netherlands
Scientific
Catharina Hospital Eindhoven, department of dermatology
Michelangelolaan 2

S Geer van der
Eindhoven 5602 ZA
The Netherlands

Eligibility criteria

Inclusion criteria

1. Patients > 18 years;

2. Primary BCC, nodular or nodular and partially superficial;

3. BCC in the face;

4. BCC size 1-5 cm in diameter.

Exclusion criteria

1. Pregnant women;

2. Women who breastfeed;

3. Recurrent BCC;

4. Agressive growth pattern (squamous, morpheaform, infiltrative);

5. BCC within 1 cm from the eyes, lips or mucosa of the nose;

6. Another skin cancer within 5cm of the target tumour;

7. Former treatment of BCC in the target area;

8. Allergy for imiquimod 5% cream or substances of the cream.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2007
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-10-2007
Application type:	First submission

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
NTR-new	NL1048
NTR-old	NTR1081
Other	METC Catharina Ziekenhuis Eindhoven : M07-1745
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A