Randomized controlled trial for the cosmetic result of intracutaneous versus transcutaneous sutures after dermatologic surgery in the face

Published: 26-03-2014
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Evaluation of the cosmetic result after 12 months of transcutaneous sutures versus intracutaneous sutures in the craniofacial area.

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

Summary

ID

NL-OMON40323

Source
ToetsingOnline

Brief title
IC versus TC sutures

Condition

- Skin neoplasms malignant and unspecified

Synonym
skin tumors

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cosmetic result, Intracutaneous sutures, Surgery, Transcutaneous sutures

Outcome measures

Primary outcome

Cosmetic result measured on the POSAS (Patient and Observer Scar Assessment Scale) by the patient and the researcher 12 months after surgery.

Secondary outcome

We will determine complications within two weeks and cosmetic result on the four-point scale (bad, average, good, excellent) after 3 and 12 months between both treatment.

Study description

Background summary

Skin cancer is common in Caucasians and often exists on sun-exposed areas, such as the face. Treatment of choice is mostly excision and result in an irreversible scar. As the incidence of skin cancer is rising, also among young people, it is important to obtain a good cosmetic outcome after treatment. It is believed that the type of closure of the wound after excision can influence the cosmetic result. Currently, primary closure of the excision can occur by transcutaneous (TC) or intracutaneous (IC) suturing. These techniques are the most often used ones among dermatologists and plastic surgeons and the choice is mainly dependent on the preference of the physician. Research comparing the cosmetic result of both techniques in the craniofacial area is lacking.

Study objective

Evaluation of the cosmetic result after 12 months of transcutaneous sutures versus intracutaneous sutures in the craniofacial area.

Study design

A randomized controlled single-blinded multi-center trial.

Intervention

Local excision followd by intracutaneous or transcutaneous sutures. In both groups sutures will be removed after zeven days and patients are asked to apply a sunscreen on the scar daily for the first three months.

Study burden and risks

All patients who participate have an indication for excision and will be assigned to one of the suture techniques. Both techniques are widely used in the regular patient care. Therefore, no extra risks are associated with it. Patients will be asked to visit the hospital 3 months and 1 year following treatment, at which point a questionnaire will be filled in and the redness of the scar will be measured by means of non-invasive techniques. The hospital visits will, if possible, be combined with regular follow-up visits.
In addition, they are asked to apply a sunscreen on the scar once daily during the follow-up of the first three months.

Contacts

Public
Maastricht Universitair Medisch Centrum

P. Debyelaan 25
Maastricht 6229HX
NL
Scientific
Maastricht Universitair Medisch Centrum

P. Debyelaan 25
Maastricht 6229HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Skin tumor (benign or maligne) in the craniofacial area of minimaal 5mm in diameter
Excision is the therapy of choice followed by primary closure
Patients of 18 years or older

Exclusion criteria

Patients better suited for non-surgical treatment
Patients suited for excision but reconstruction by transplantation, flaps, or secundary granulation is necessary

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-11-2014
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
ClinicalTrials.gov	NCT02125058
CCMO	NL46056.068.13

Study results

Date completed:	10-02-2016
Actual enrolment:	140