Surgical and aesthetic outcome, quality of life, and cost-effectiveness of keloid treatment

Published: 29-06-2012
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Finding an effective and permanent treatment against keloid.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON39619

Source
ToetsingOnline

Brief title
Keloid

Condition

- Epidermal and dermal conditions

Synonym
Excessive scar tissue, fibroproliferative disorder

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,Fonds NutsOhra zorgsubsidies

Intervention

Keyword: Brachytherapy, Intralesional cryotherapy, Keloid, Quality of Life

Outcome measures

Primary outcome

Primary endpoint is POSAS score.

Secondary outcome

Secondary endpoints are volume reduction, Skindex-29, SF-36, ED-5Q, QST,

histology, appearance of adverse reactions and indication for further

treatment.

Study description

Background summary

When the complex process of dermal healing is disturbed this can result in excessive scarring. Keloid disease is a tumorous scar that grows outside of wound borders. It appears as a raised, vascular, pigmented lesion that gives rise to aesthetic and psychosocial complaints, itching, and pain. Adequate treatment is indicated, but because of variable results and recurrence of the keloid current therapies are suboptimal. There is a lack of randomized studies comparing treatments, thereby no hard evidence favoring one treatment over another exists and many suboptimal treatments are in practice.

Study objective

Finding an effective and permanent treatment against keloid.

Study design

Comparing intralesional cryotherapy for keloid disease with current best practice treatment on objective and subjective outcome.
We will do this by a randomized controlled intervention study consistent of 2 parts;
1) for primary keloids comparing intralesional cryotherapy with excision combined with corticosteroid injections.
2) for recurrent keloids comparing intralesional cryotherapy with excision

combined with brachytherapy.
This results in a total of 4 study arms; 2 in both parts of the study.

Intervention

1) Primary keloids: intralesional cryotherapy or extralesional excision with adjuvant triamcenolonacetonide 40mg/ml injections starting 2 weeks post operative.
2) Recurrent keloids: intralesional cryotherapie or extralesional excision with adjuvant Ir-192 brachytherapy (18Gy in 2 dosis within 8 hours post operative).

Study burden and risks

Patients will receive regular treatments participating in this study; however they cannot choose which treatment they receive. Burdens associated with the treatments are similar as when they would have been treated regularly. Completion of the questionnaires will take an additional 20 to 50 minutes on intake and all 4 follow-up visits. The questionnaires may contain personal or confronting questions. We ask patients specially for permission to take a 3mm biopsy on after treatment for histological measurements. The keloids included have a minimum size of 1x1 cm and are often much bigger, the biopsy is a small sample compared to the scar present. Injury can activate keloid.

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

Keloid patients, 18-75 yr old, full mental competence, sufficient knowledge of Dutch or English language, keloid suitable for primairy closure after excision, minimum keloid size of 1x1cm.

Exclusion criteria

Hypertrofic scars. Keloids less than 1 year existent, burn scars, pregnancy, previous radiotherapy which prohibits additional rediotherapy (only for the group of recurrent keloids), hypersensitivity for lidocaine, adrenaline, triamcinolone. Chronic use (>1 month) of systemic corticosteroids, or immunosuppressive medication (e.g. TNF alfa inhibitors). Use of systemic chemotherapy. Severe morbidity with a life expectancy of less than one year.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2012

Enrollment:	176
Type:	Actual

Medical products/devices used

Generic name:	Cryoshape
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Kenacort-A '40'
Generic name:	triamcenolone acetonide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-06-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-09-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-02-2014
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-03-2014
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

ID: 22731
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-002675-34-NL
CCMO	NL40235.078.12
OMON	NL-OMON22731