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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22731

Source
Nationaal Trial Register

Health condition

keloid

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Outcome measures

Primary outcome

Patient Observer Scar Assessment Scals score.

Secondary outcome

Volume reduction, Skindex-29, SF-36, ED-5Q, appearance of adverse reactions, patient statisfaction.

Study description

Background summary

This is a multicentre randomised controlled open trial that compares surgical keloid treatments with validated PROMs as outcome measures. The outcomes of this study will improve evidence-based decision-making for the treatment of keloids, as well as patient education.

Study objective

Intralesional cryotherapy for keloid treatment is better than excision with either corticosteroid injections or brachytherapy post-operative.

Study design

baseline, and 2, 12, 26 and 52 weeks postoperatively

Intervention

Primary keloids: intralesional cryotherapy or extralesional excision with adjuvant triamcenolonacetonide 40mg/ml injections starting 2 weeks post operative.
Resistant keloids: intralesional cryotherapie or extralesional excision with adjuvant Ir-192 brachy therapy 12-18Gy in 2 or 3 fractions within the first 2 post operative days.

Contacts

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Eligibility criteria

Inclusion criteria

Keloid patients, keloid >1x1 cm, 18-75 yr old, full mental competence, sufficient knowledge of Dutch or English language, keloid suitable for primary closure after excision.

Exclusion criteria

Hypertrophic scars, keloids < 1yr old, burn scars, pregnancy, use of chemotherapy, chronic use of corticosteroids or immonosuppressors, life expectancy < 1 yr, hypersensitivity for lidocaine, epinephrine, triamcenolone acetonide

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	26
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 21-08-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39619
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3979
NTR-old	NTR4151
CCMO	NL40235.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39619

Study results

Summary results
N/A