Perforator based interposition flaps for sustainable release of scar contractures: a reliable, simple and versatile technique.

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A randomised controlled multcenter trial is performed to evaluate the perforator-based interposition plasty in comparison to full thichness grafts for scar contracture releases.

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

Summary

ID

NL-OMON39449

Source
ToetsingOnline

Brief title
Perforator based interposition plasty

Condition

- Epidermal and dermal conditions
- Skin and subcutaneous tissue therapeutic procedures

Synonym
scarcontracture, tightening of the skin after skin transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Brandwondencentrum

Source(s) of monetary or material Support: Nederlands brandwonden stichting

Intervention

Keyword: contracture release, interpositionplasty, perforators, scar contraction

Outcome measures

Primary outcome

The contraction of the flap/graft after three and twelve months is the primary

outcome measure.

Secondary outcome

Secundary outcome parameters are necrosis, pigmentation, flap elasticity, range

of motion and cosmetic outcome.

Study description

Background summary

Scar contraction after transplantation of the skin, remains a considerable problem and reconstruction is frequently indicated. Local flaps offer the best quality of tissue (normal skin and subcutaneaous fat) but the usage is limited by availability and vascularisation. Since the discovery of perforators many types of new skin flaps can be harvested as long as it incorporates a perforator bundle of an artery and a vein. Based on literature and our own experience we present a concept of a flap design based on perforator vessels and local available skin. This concept should lead to an increased functional outcome and flap survival. The implications of the use of perforator based flaps for scar surgery by means of a RCT have to be determined yet.

Study objective

A randomised controlled multcenter trial is performed to evaluate the perforator-based interposition plasty in comparison to full thichness grafts for scar contracture releases.

Study design

Patients who require surgery for release of a scar contracture in one of the

three burn centers, are eligable for this study. Prior to surgery, perforators will be identified by Doppler in the adjacent area of normal skin. A peninsular flap will be designed. Measurements are performed (length, width, angle of rotation, and the surface area of the flap). Then, the treatment is allocated by randomisation. Follow up will take place after 1 and 3 weeks for survival and after 3 and 12 months for contraction, as well as flap elasticity, colour, range of motion and cosmetic outcome.

Intervention

Full thickness graft versus perforator-based interposition flap.

Study burden and risks

For patients undergoing the new technique no extra riscs are expected in comparison to the stnadard technique: a full thickness graft. We expect that the perforator based interposition flap results in an increase of the surface area and an increased survival and fast wound healing because of the adequate vascularisation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Indication for release of scar contracture
Sufficient tissue for a perforator based interposition flap
Able to give informed consent

Exclusion criteria

Age >= 12 years
Location: scars on face or scul
Smoking: the patient is eligiable if smoking is quit for > 3 weeks before the operation
Psychiatric disorders (if a problematic follow-up is anticipated)
Language barrier

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	09-05-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	18-12-2011
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	27-11-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	18-03-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL34053.094.10