Stromal Vascular Fraction injectable as a preventive treatment of scars.

No registrations found.

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

Summary

ID

NL-OMON22350

Source
NTR

Brief title
POSAS Trial (Prevention of Scars with Adipose Stroma)

Health condition

Scar formation, scars, wound healing.

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: University Medical Center Groningen (UMCG)

Intervention

Outcome measures

Primary outcome

POSAS questionnaires, both observer as patient questionnaire.

Secondary outcome

Immunohistological stainings of biopsies.

RNA isolation out of biopsies.

Standardised photographs.

Study description

Background summary

In this prospective study we investigate the potential effect of Stromal Vascular Fraction (SVF)

injection as a preventive treatment of scar formation after mamma reduction. All patients will receive

SVF (0,1 ml per 0,5 cm2 scar surface) in 1 scar of 1 breast and 0,9% NaCL (0,1 ml per 0,5 cm2 scar

surface) in the other scar of the breast. Only the lateral side (till 5 cm from the edge) of the horizontal

scar will be treated and investigated in both breasts. SVF will be created by using a mechanical

dissociation procedure named: the FAT (Fractionation of Adipose Tissue) procedure. Postoperative

clinical improvement is measured with the POSAS questionnaire containing the observer scar

assessment and the patient scar assessment and will focus on: vascularization, pigmentation,

thickness, relief, pliability, pain, itchiness, stiffness and irregularity. 1 questionnaire (patient and

observer assessment) is completed for each breast. Postoperative scar improvement is also

measured by RNA isolation and histological observation of biopsies (into the dermal fat layer) on fixed

positions. Histological observation will focus on extracellular matrix remodeling, epidermis renewal,

cell infiltration and new microvasculature formation. RNA isolation will focus on pro- and anti-

inflammatory genes. 1 biopsy is taken of each breast every time. Postoperative improvement

is

analyzed by a photographic panel assessment. Photographic evaluation will focus on scar size

reduction, change of color and relief using a Visual Analogue Scale (VAS).1 photograph is taken of

each breast every time. All measurements will be done on predetermined time-points: 6 months and

12 months postoperative, only the biopsies will be taken preoperative as well.

Study objective

Stromal Vascular Fraction injection in the wound edges will prevent scar formation after a mammae reduction compared to a placebo injection.

Study design

Preoperative, 6 months and 12 months postoperative.

Intervention

Stromal Vascular Fraction injection obtained by mechanical dissociation of adipose tissue. 1 ml of Stromal Vascular Fraction will be injected in the lateral 5 cm of the horizontal scar after a mamma reduction.

Contacts

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Eligibility criteria

Inclusion criteria

• Females

• Age 18-50

• Mamma reduction in both mammae, wise pattern

Exclusion criteria

• Male

• Aged below 18 or above 50 years

• Aged between 18 and 50 and in the menopause or pre-menopause

• Surgical interventions of the breasts in the year prior to the date of surgery

• Mammareduction of 1 mamma

• Any oncological event in the patients history

• A known psychiatric condition

• A known systemic disease that will impair wound healing (e.g. diabetes mellitus, known atherosclerosis with an event that required hospitalization, collagen diseases, diseases of the skin, HIV).

• Prednisone or other immunotherapy

• Smoking

• Pregnancy or active child wish

• Frequent exposure to known carcinogenic substances (e.g. work related).

• Active or previous use of hormone replacement therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	38
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47353
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5613
NTR-old	NTR5719
CCMO	NL55651.000.16
OMON	NL-OMON47353

Study results