Stromal Vascular Fraction injectable as a preventive treatment of scars.

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22350

Bron
NTR

Verkorte titel
POSAS Trial (Prevention of Scars with Adipose Stroma)

Aandoening

Scar formation, scars, wound healing.

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: University Medical Center Groningen (UMCG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

POSAS questionnaires, both observer as patient questionnaire.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Preoperative, 6 months and 12 months postoperative.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Females

• Age 18-50

• Mamma reduction in both mammae, wise pattern

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2016
Aantal proefpersonen:	38
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-04-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47353
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten