Stromal Vascular Fraction injectable as treatment of adherent burn scars.

Published: 23-10-2020
Last updated: 10-01-2025

To assess the change in scar pliability measured by the Cutometer (primary outcome) pre- and 12 months post grafting and to quantify clinical and histological improvements of scar characteristics with the combination therapy of SVF enriched fat...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON49720

Source
ToetsingOnline

Brief title
SVF injectable as treatment of burn scars.

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Burn scars, fibrosis, hypertrophic skin

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Burn scars, Fat grafting, Stromal cells, Stromal vascular fraction

Outcome measures

Primary outcome

The primary outcome parameter is change in scar pliability, measured by the Cutometer Skin Elasticity Meter 575 (Courage and Khazaka GmbH, Cologne, Germany) between pre- and 12 months post grafting.

Secondary outcome

Change in scar pliability, retraction, elasticity, viscoelasticity and maximum extension between pre- and 3 months and 3- and 12 months post SVF enriched grafting will be analysed. Change in retraction, elasticity, viscoelasticity and maximum extension will also be analysed between pre- and 12 months post grafting.

Change in the quantity of melanin and erythema will be measured with the DSM II ColorMeter (Cortex Technology, Hadsund, Denmark) immediately before (i.e. within 24 hours before treatment) and at 3 and 12 months post grafting.
Change in quantity of melanin and erythema will be analysed between pre- and 3 months post grafting and between 3 months and 12 months post grafting.

Change in scar quality will be measured with the Patient and Observer Scar Assessment Scale (POSAS), immediately before (i.e. within 24 hours before treatment) and at 3 and 12 months post grafting.

Changes in the POSAS Patient and Observer scale will be analysed between pre-

and 3 months post grafting and between 3 months and 12 months post grafting.

Histological changes of the scar are objectified by taking 2 mm biopsies of the dermal fat on fixed positions, just before treatment and at 12 months follow up. For patients to participate in our research, this histological part is optional. Histological observation will focus on extracellular matrix remodelling, epidermis renewal, cell infiltration and new microvasculature formation.

Study description

Background summary

Fat grafting is regarded as a promising and novel technique in the treatment of adherent scars. This is strongly supported by evidence-based clinical trials as well as fundamental studies in animals and in vitro. Recently, acquiring Stromal Vascular Fraction (SVF), containing adipocyte stromal cells (ADSCs), out of lipoaspirate became easier with a fast-non-enzymatic intra-operative procedure. ADSCs increase angiogenesis, can induce mitosis in resident tissue cells and are able to remodel collagen. The hypothesis is that SVF can therefore be beneficial in the treatment of adherent scars. In previous adherent scar research, it*s also stated that the enrichment of fat grafts with ADSCs should be explored.

To investigate the potential beneficial effect of SVF on scars, we set up a collaboration between two Dutch Burn Centres, *Red Cross Hospital Beverwijk* and *Martini Hospital Groningen*, and the Tissue Engineering department (Medical Biology) of the University and Medical Centre Groningen (UMCG).

Our aim in this study is to investigate the potential beneficial effect of SVF enriched fat grafting (combination therapy), containing ADSCs, on pliability of adherent scars.

Study objective

To assess the change in scar pliability measured by the Cutometer (primary outcome) pre- and 12 months post grafting and to quantify clinical and

histological improvements of scar characteristics with the combination therapy of SVF enriched fat grafts.

Study design

Prospective longitudinal multi-centre cohort study.

Intervention

Patients will receive SVF enriched fat graft injection (ratio SVF: fat =1:10) underneath an adherent scar.

Study burden and risks

All measurement moments will take around 30 minutes. The pre-op measurements are combined with the surgical procedure and the 3 months post-op measurement is combined with a regular 15-minute follow-up visit at 3 months. For the 12 months follow up visit, the patient will visit the outpatient clinic for the study only and will be compensated for travel expenses. The duration of the operation is estimated at 1.5 hours. One hour for fat grafting of other scars (standard care), and maximum half an hour extra for the intervention: optionally taking a 2mm biopsy, liposuction, production of SVF, mixing the fat graft with SVF and adhesiolysis and injection under the scar (of which 10 minutes is standard care).
A 2mm biopsy of the adherent scar is optional for patients and performed by a plastic surgeon under full or local anaesthesia at two time-points, one during the operation (i.e. pre-grafting, full anaesthesia) and one at the 12 months follow up visit (local anaesthesia).

Contacts

Public
Rode Kruis Ziekenhuis

Vondellaan 13
Beverwijk 1942LE
NL
Scientific
Rode Kruis Ziekenhuis

Vondellaan 13
Beverwijk 1942LE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients seen by the plastic surgeon in Burn Centre Beverwijk or Groningen with adherent scars caused by burns, necrotic fasciitis or degloving injury with no history of prior surgical treatment of the scar, other than skin transplantation.
- Minimum age of 18
- Patient has an adherent scar (minimum scar age: 12 months) caused by burns, necrotic fasciitis or degloving injury, for which fat grafting is indicated
- Competent adults

Exclusion criteria

- Previous scar treatment with fat grafting in selected scar
- General exclusion criteria for fat grafting procedure: pregnancy, BMI < 18
- Skin melanoma in patient*s history
- Unwillingness to commit to the study protocol and show up for all follow up moments
- Insufficient proficiency in Dutch to the extent that clear communication is not possible

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	46
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-10-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
Other	NL 8461
CCMO	NL72094.000.20

Study results

Summary results
Trial never started