Stromal Vascular Fraction as treatment of adherent scars.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26667

Source
NTR

Brief title
SVF For Burn Scars

Health condition

Scars, scar formation, burns, burn scars, adherent scar

Sponsors and support

Primary sponsor: ZonMw, Nederlandse Brandwondenstichting
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Pliability by the cutometer

Secondary outcome

POSAS questionnaires, both observer as patient questionnaire.

DSM colormeter
Cutometer other variables
Immunohistological stainings of biopsies.
RNA isolation out of biopsies.

Study description

Background summary

Fat grafting is recognized 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 the 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, compared with fat grafting, the current standard of care.

Study objective

Stromal Vascular Fraction injection underneath burn scar will improve pliability of the scar more than fat grafting (historical cohort).

Study design

Preoperative, 3 months and 12 months postoperative.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

• Patients seen by a plastic surgeon in Burn Centre Beverwijk or Groningen
• Patient is ≥ 18 years old
• 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 controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-04-2020
Enrollment:	42
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8461

Register ID

Other	ZonMw Medische Producten Nieuw en Nodig (MPNN) : MPNN 427002011

Study results

Summary results

N/A