

Stromal Vascular Fraction (SVF) enriched lipofilling plus Platelet Rich Plasma (PRP) for the treatment of the aging face.

No registrations found.

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

Summary

ID

NL-OMON20000

Source

NTR

Brief title

PRS (Platelet Rich Stroma) Trial

Health condition

Ageing of the face, skin quality improvement.
Veroudering van het gelaat, huidkwaliteit verbetering.

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: Bergman Clinics Rijswijk
Arthrex Germany

Intervention

Outcome measures

Primary outcome

Cutometer and tewameter

Secondary outcome

VISIA complexion analysis, FACE-Q questionnaire, photographic analysis

Study description

Background summary

In this prospective study we investigate the potential beneficial effect of adding a Stromal Vascular

Fraction (SVF) to Platelet Rich Plasma (PRP) + lipofilling. Amelioration of skin quality improvement of

the aging face is anticipated. One group will receive lipofilling + PRP + SVF and the other group will

receive lipofilling + PRP + 0,9% NaCl solution. SVF will be created by using a mechanical dissociation

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

measured with a Multi Probe Adapter system (Courage Khanza Colone Germany) containing two skin

measurement probes (Cutometer MPA580: Mechanical parameters of the skin and Tewameter

TM300:Skin barrier function and transepidermal water loss,) on predetermined fixed positions in the

face. Postoperative improvement is analyzed by a photographic panel assessment as well. Panel

evaluation will focus on volume restoration and remaining volume over time. Postoperative skin

parameters are measured in a predetermined fixed mask in the face, with a VISIA® Complexion

Analysis (Canfield Scientific Inc.) containing several parameters: skin texture, wrinkle depth, porien

and brown and red spots. Standardized FACE-Q questionnaires will focus on satisfaction after the

treatment, social wellbeing and recovery. All measurements will be done on predetermined time-

points: preoperative, 6 weeks, 3 months, 6 months, 12 months postoperative.

Study objective

Stromal Vascular Fraction enriched lipofilling in combination with Platelet Rich Plasma (PRP) increases skin quality improvement as compared to lipofilling in combination with PRP alone.

Study design

6 weeks, 3 months, 6 months and 1 year.

Intervention

Group A: Stromal Vascular Fraction injection, Platelet Rich Plasma injection, lipofilling

Group B: Platelet Rich Plasma injection, lipofilling, 0.9% NaCl injection

Contacts

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Eligibility criteria

Inclusion criteria

- Females
- Age 35-60
- Stable normal BMI (20-25) (1 year stable between 20-25)

Exclusion criteria

- Male
- Aged below 35 or above 50 years
- Aged between 35 and 50 and in the menopause or pre-menopause
- Surgical interventions of the face in the year prior to the date of surgery
- 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).
- Smoking
- $20 > \text{BMI} > 25$ or an unstable BMI: 1 year \pm 5 points.
- 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:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	16-02-2016
Enrollment:	64
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	07-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46886
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register

NTR-new

NTR-old

CCMO

OMON

ID

NL5597

NTR5703

NL54409.000.15

NL-OMON46886

Study results