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

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Stromal vascular fraction enriched lipofilling + PRP is believed to ameliorate current results in comparison to treating skin quality of the aging face by lipofilling+ PRP only.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46886

Source
ToetsingOnline

Brief title
SVF + lipofilling + PRP for the treatment of the aging face.

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
atrophy of the skin, Loss of skin quality, loss of volume

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Arthrex ,Bergman Clinics,Bergman Clinics;Arthrex

Intervention

Keyword: Huidkwaliteit verbetering, Lipofilling, Platelet rich plasma, Stromal Vascular Fraction

Outcome measures

Primary outcome

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 waterloss,) on predetermined fixed positions in the face on predetermined times (preoperative, 6 weeks, 3 months, 6 months and 1 year postoperative).

Secondary outcome

Scores derived from standardized photographic assessment by two separate panels. The method used for assessment is based on methods described by Moolenburg and Strasser. Output parameter is a visual analogue score ranging from 0 (very poor facial volume) to 10 (excellent facial volume), and for skin quality 0 (pour skin quality) to 10 (excellent skin quality).

Results of the patient questionnaire (FACE-Q) with the following endpoints, for example: number of complications, Return to work/Return to social activities and a patient evaluation of their own appearance using a visual analogue scale. This questionnaires will use the standardized FACE-Q list and will be completed during the following moments: preoperative, 6 weeks, 6 months, 12 months postoperative.

Improvement in local skin parameters measured with the VISIA® Complexion Analysis (Canfield Scientific Inc.). Measurements will be done on a fixed mask for every subject on 4 separate moments in time: 6 weeks, 3 months, 6 months and 1 year post-operative in comparison to pre-operative measurements.

Study description

Background summary

Soft tissue augmentation by the means of lipofilling is nowadays a frequently used technique in all forms of plastic surgery. In aesthetic facial surgery it has shown to increase the rejuvenating effect, in reconstructive surgery it has earned its place in the correction of soft tissue defects and athropy. Post-operative loss of the transplanted fat remains an uncertain factor in the procedure. In current literature, there are three main hypotheses on aetiology of postoperative loss of transplanted adipocytes, resulting in decrease of the grafted volume 1: reduced viability of the injected fat cells 2: impaired graft revascularization at the target site 3: reduced ingrowth at the target site due to fibrosis in the target area. Mentioned factors have limited the application of (large) volume lipotransfer.

We have witnessed unexpected improvement of skin quality, similar positive effects of lipofilling on skin quality have been reported by others. Coleman observed softening of wrinkles, decreasing pore size and pigmentation improvements on graft sites. Possible mechanisms of the claimed regenerative properties of the lipograft are explained by the high number of Adipose Derived Stem Cells. Because of the different names for Adipose Derived Stem Cells in literature, we have decided to name these cells fat stem cells when we are referring to Pericytes, Adipose Mesenchymal Stem Cells, Pre-Adipocytes, Adipose Stromal Cells or Adipose Derived Stem cells. Although this phenomenon frequently described in literature, no objective clinical results from prospectively randomised studies have ever been performed up to today.

In this prospective study we investigate the potential beneficial effect of adding stromal vascular fraction (with fat stem cells and small blood vessels) to the state of the art treatment in facial plastic surgery (PRP + lipofilling). Amelioration of skin quality improvement of the aging face is anticipated. One group will receive lipofilling + PRP + stromval vascular fraction and the other group will receive lipofiling + PRP + 0,9% NaCl solution. Lipofilling and PRP have already proven their beneficial effect on skin quality. They can be considered the golden standard in autologous

treatment of aging skin.

We are particularly interested in the stromal vascular fraction (with fat stem cells and small blood vessels) injectables. Fat stem cells are regenerative cells from adipose tissue, which can be easily isolated from lipoaspirate where they probably are adjacent as pericytes to little blood vessels. It is well known that fat stem cells can differentiate into ectodermal, endodermal and mesenchymal differentiated cells. The possibility to differentiate into vascular mural cells results in the promotion of angiogenesis and graft survival. Most important role of fat stem cells is the conduction of the adipose tissue turnover. Suctioned fat seems to lose a number of fat stem cells during the liposuction and preparation phase compared to not suctioned fat. To maximize the biological function and the differentiation capacity of lipofilling, stromal vascular fraction is added. We developed a method to dissociate stromal vascular fraction from lipoaspirate (by mechanical dissociation of lipoaspirate without the addition of any enzymatic or chemical substrates).

We trust the outcome of this study will ameliorate the current limitation of lipofilling, especially large volume lipotransfer (allowing reconstruction in one procedure instead of multiple with smaller volumes), and lipofilling in pour vascularised tissue (eg. fibrosis after radiation therapy) by the addition of stromal vascular fraction injectables. Furthermore, the suggested local skin improvements could be used in scar revisions and burn treatment in the future, bypassing invasive surgery.

Study objective

Stromal vascular fraction enriched lipofilling + PRP is believed to ameliorate current results in comparison to treating skin quality of the aging face by lipofilling+ PRP only.

Study design

Prospective double blind randomized controlled trial

Intervention

The Colemen technique for fat harvesting and injection is employed but refined by utilising a smaller, custom-made cannula for harvesting (inner diameter, 1,3mm). The upper legs are donor sites. 3/4 of the usual amount of harvested fat will be harvested extra. Fat is centrifuged for 2,5 minutes at the maximum speed of 3000 revolutions per minute after which the oil layer (top) and serum/infiltrate layer (bottom) are drained away, preserving the middle stromal vasculair fraction and the pellet. Fat injection is performed in 1-mm aliquots with a short, curved Coleman cannula. 15 ml of fat is injected into the deep

subcutaneous plane of each side of the face, except for the lower lid/tear trough region (where the injection is performed in the supraperiosteal/submusclar plane) and the temporal area (where the level of injection as above the superficial fascia of the temporal muscle).

All patients will receive lipofilling by the Coleman technique + the addition of 2,5ml of PRP in each side of the face. Patients in group A will receive a 1ml injection of stromal vascular fraction in each side of the face and patients in group B will receive a 1ml solution of 0,9% NaCl in each side of in the face.

Study burden and risks

Of each included subject 55 ml of venous blood and 160 ml of lipoaspirate will be drawn before the start of the operation. Subjects will already be under full sedation anaesthesia at the time of the preparation and injection of fat stem cell injectables or injection of 0,9% NaCl.
After a period of 6 weeks, 3 months, 6 months and 1 year, additional visits are scheduled for the second, third, fourth and fifth measurements with the Multi-probe system. In addition, the second, third, fourth and fifth measurements with the VISIA® will be performed. Duration of each measuring session is estimated at 35 minutes.

Potential risk of the included subject is low: PRP has been in use as an adjuvant since 1985. No health risks or (serious) adverse events have been reported to this date. PRP is currently used for several applications in domestic and foreign hospitals. Stromal vascular fraction enriched lipofilling has not ever increased health risks nor has showed to increase adverse events of any kind to this date.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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

Exclusion criteria

• Male
• Aged below 35 or above 60 years
• 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• 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2016
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2016
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	31-05-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-12-2018
Application type:	Amendment
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

ID: 20000
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54409.000.15
OMON	NL-OMON20000

Study results

Results posted: 22-12-2020

Summary results
Trial ended prematurely

First publication
22-12-2020