

Predictors of the volumetric outcome and patients' satisfaction of facial fat grafting.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Age related factors
Study type	Observational invasive

Summary

ID

NL-OMON41719

Source

ToetsingOnline

Brief title

Predictors of facial fat grafting

Condition

- Age related factors
- Skin and subcutaneous tissue therapeutic procedures

Synonym

autologous fat transplantation, fat graft, lipofilling

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Facial fat graft, Patient satisfaction, Predictors, Volumetric outcome

Outcome measures

Primary outcome

The primary objective is volumetric changes from baseline to one year after fat grafting measured by 3d stereophotogrammetry and calculated using 3D software.

All the patients will get series of 3D photographs of the face preoperatively (baseline) and twelve months postoperatively. The injected volume during the fat graft procedure will be noted. The change in volume measured by 3d stereophotogrammetry will be related to injected volume, bodyweight, smoking habits, 17 β oestradiol level and/or the post-menopausal state.

Secondary outcome

The secondary objectives are:

- * patient satisfaction about their facial appearance, psychological wellbeing and social function preoperatively, and after 1 week, 6 weeks, 6 months, and 12 months after the procedure measured by the validated FACE-Q questionnaire.
- * the evaluation of volumetric changes during the follow up measured at 6 weeks, 6 months, and 12 months.
- * relation of patients' satisfaction and the volumetric outcome of their facial fat graft measured by 3d stereophotogrammetry at different time points.

Study description

Background summary

Autologous fat grafts are commonly used in reconstructive and aesthetic surgery. The retention of the transplanted fat is 20-90%. The predictors of this volume retention remain unclear.

Study objective

The first objective of this study is to assess the volumetric changes from baseline one year after fat grafting measured by 3d stereophotogrammetry (3dMD). The observed level of fat retention will be related to injected volume, bodyweight, smoking habits, 17 β oestradiol level and/or the post-menopausal state. The second objective is to assess the change in patient satisfaction by a (translated) validated questionnaire (FACE-Q).

Study design

This study is a prospective cohort study.

Study burden and risks

The burden and risks for patients who will join this research project are thought to be very low if any. The burden for the patient is to complete short questionnaires and to undergo one extra blood draw (one tube) at baseline. The benefits from this research project are that new insights will be obtained how to make reliable surgical plans in the future. Moreover, patients will be better informed on forehand about the expected results of fat grafting in advance.

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

Women

Age between 18 and 75 year

Facial fat graft procedure at the department of Oral Maxillofacial surgery of the University Medical Center Groningen

Exclusion criteria

Children (<18 years)

Men

Patient older than 75 years

Pregnancy at the moment of the fat graft procedure

Contraindications for fat grafting: ASA class 3 or 4, coagulation disorders, body dysmorphic disorder, use of anticoagulantia what can not be stopped for this procedure, medication with interference with cytochrome P450, 3A4 or 1A2

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2015
Enrollment:	116
Type:	Actual

Ethics review

Approved WMO	
Date:	12-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	10-02-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL51511.042.14