

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON29158

### Source

Nationaal Trial Register

### Brief title

LIPOFILLING

### Health condition

Fat graft  
Lipofilling  
Autologous fat transplantation  
Volumetric outcome  
Predictors  
Patient satisfaction

Vet transplantatie  
Lipofilling  
Volumetische uitkomst  
Voorspellers  
Patient tevredenheid

## Sponsors and support

**Primary sponsor:** University Medical Center Groningen; department of Oral and Maxillofacial Surgery

**Source(s) of monetary or material Support:** University Medical Center Groningen; department of Oral and Maxillofacial Surgery

## Intervention

## Outcome measures

### Primary outcome

Volumetric differences between baseline and 1 year after fat grafting measured by 3d stereophotogrammetry

### Secondary outcome

Patient satisfaction measured by FACE-Q questionnaire

## 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. This study aims to relate patient's bodyweight, smoking habits, estradiol level and the post-menopausal status to the volumetric outcome and satisfaction of patients after facial fat grafting. The design of the study is a prospective observational cohort study with invasive measurements.

All patients who will undergo a facial fat graft procedure at the department of Oral and Maxillofacial Surgery at the University Medical Center Groningen (the Netherlands) will be included.

Volumetric outcome will be measured by 3D stereophotogrammetry at 6 weeks, 6 months, and 12 months. Patient satisfaction will be evaluated by the FACE-Q questionnaire. 17 $\beta$  oestradiol and AMH measurements will be generalized using a blood sample. Burden risk of participation the study thought to be very low.

### Study objective

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. This study aims to relate patient's bodyweight, smoking habits, estradiol level and the post-menopausal status to the volumetric outcome and satisfaction of patients after facial fat grafting.

The hypothesis is that smoking and low estradiol levels will influence the volumetric outcome negatively.

### **Study design**

Preoperative (4-6 weeks preoperatively)

1 week postoperatively

6 weeks postoperatively

6 months postoperatively

12 months postoperatively

### **Intervention**

Facial fat grafting

## **Contacts**

### **Public**

Mondziekten, Kaak- en Aangezichtschirurgie - University Medical Center Groningen

A.J. Tuin  
Hanzeplein 1

Groningen 9713GZ  
The Netherlands  
(0031) 050-3613846

### **Scientific**

Mondziekten, Kaak- en Aangezichtschirurgie - University Medical Center Groningen

A.J. Tuin  
Hanzeplein 1

Groningen 9713GZ  
The Netherlands  
(0031) 050-3613846

## **Eligibility criteria**

## Inclusion criteria

Women

Age between 18 and 75 years

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

## Exclusion criteria

Children (under 18 years)

Men

Patients 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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2015
Enrollment:	100

Type: Anticipated

## Ethics review

Positive opinion

Date: 23-07-2015

Application type: First submission

## 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	NL5177
NTR-old	NTR5325
Other	METc UMCG : METc 2014/500

## Study results

### Summary results

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