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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29158

Bron
Nationaal Trial Register

Verkorte titel
LIPOFILLING

Aandoening

Fat graft
Lipofilling
Autologous fat transplantation
Volumetric outcome
Predictors
Patient satisfaction

Vet transplantatie
Lipofilling
Volumetische uitkomst
Voorspellers
Patient tevredenheid

Ondersteuning

Primaire sponsor: University Medical Center Groningen; department of Oral and Maxillofacial Surgery
Overige ondersteuning: University Medical Center Groningen; department of Oral and Maxillofacial Surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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. 17b oestradiol and AMH measurements will be generalized using a blood sample.
Burden risk of participation the study thought to be very low.

Doel van het onderzoek

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.

Onderzoeksopzet

Preoperative (4-6 weeks preoperatively)

1 week postoperatively

6 weeks postoperatively

6 months postoperatively

12 months postoperatively

Onderzoeksproduct en/of interventie

Facial fat grafting

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women

Age between 18 and 75 years

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 dismorphic disorder, use of anticoagulantia what can not be stopped for this procedure, medication with interference with cytochroom P450, 3A4 or 1A2

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-07-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5177
NTR-old	NTR5325
Ander register	METc UMCG : METc 2014/500

Resultaten

Samenvatting resultaten

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