Effectiveness of septoplasty.

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Nasal obstruction is one of the most common reasons for nasal surgery and a deviated nasal septum is the most common anatomical cause of nasal obstruction. Accordingly, septal surgery is one of the most common procedures in ENT practice. There is an...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23394

Bron
NTR

Verkorte titel
Septum-trial

Aandoening

- septoplasty
- effectiveness
- nasal septum
- randomised trial
- quality of life
- cost

Ondersteuning

Primaire sponsor: Radboud University Medical Center Nijmegen
Overige ondersteuning: ZONMw (projectnr. 80-83700-98-132007)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Heath related quality of life measured with the validated Glasgow Benefit Inventory questionnaire.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Surgical correction of a deviated nasal septum (septoplasty) is the most common ENT operation in adults in the Netherlands. Indications for this intervention are practice-based rather than evidence-based and internationally accepted guidelines are lacking. Subsequently, the Dutch rate of septoplasties appears to be higher than that in most other Western countries.

Objective:

What is the effectiveness of septoplasty compared to a watchful waiting strategy in adults in terms of health related quality of life and nasal passage? What is the relation between costs and effects of this procedure?

Which patients benefit most from the operation?

Study design:

Open multi-centre randomized controlled trial.

Study population:

Two hundred adults selected for septoplasty according to current medical practice.

Intervention:

Septoplasty performed within 6 weeks after randomization versus a non-surgical or watchful waiting strategy.

Follow-up:

Two years including symptom and cost diaries and scheduled follow-up visits at 0, 3, 6, 12 and 24 months.

Primary outcome measure:

Health related quality of life.

Secondary outcome measures:

Objective measurement of nasal patency, symptoms score, and costs.

Data analysis:

Effects will be calculated as incidence rate differences and incidence rate ratios, with 95% confidence intervals. Quality of life data will be analyzed with Student T- tests and analyses of variance (ANOVA). All analyses will be performed on an intention-to-treat basis. Costs per QALY will be estimated. Incremental cost-effectiveness ratios with 95% CIs will be calculated, and a budget impact analysis will be performed.

Doel van het onderzoek

Nasal obstruction is one of the most common reasons for nasal surgery and a deviated nasal septum is the most common anatomical cause of nasal obstruction. Accordingly, septal surgery is one of the most common procedures in ENT practice. There is an urgent call for such guidelines. Both the UK and Dutch ENT-societies recently indicated the 'effectiveness of septoplasty' as one of their most important gaps in medical knowledge. The objective of the current proposal therefore is to study the effects of septoplasty as compared to watchful waiting.

Onderzoeksopzet

1. Baseline;

2. 3 months;

3. 6 months;

4. 12 months;

5. 24 months.

Onderzoeksproduct en/of interventie

Septoplasty, i.e. surgical correction of a deviated nasal septum according to the current medical practice. The control group will be a watchfull waiting strategy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients selected for septoplasty with or without concurrent turbinate surgery according to current medical practice, i.e. symptomatic impairment of the nasal passage due to a septal deviation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients selected for septoplasty due to a septal perforation;

2. Patients with previous septal surgery;

3. Patients who undergo a septoplasty as part of a cosmetic rhinoplasty procedure;

4. Patients with untreated allergic rhinitis or allergic rhinitis unresponsive to medical treatment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-02-2013

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	NL3698
NTR-old	NTR3868
Ander register	WHO: The Universal Trial Number (UTN) : U1111-1139-7254
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A