Effectiveness of septoplasty.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23394

Source
NTR

Brief title
Septum-trial

Health condition

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

Sponsors and support

Primary sponsor: Radboud University Medical Center Nijmegen
Source(s) of monetary or material Support: ZONMw (projectnr. 80-83700-98-132007)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. EQ-5D;

2. SNOT-22;

3. Nasal patency measured with 4-phase rhinomanometry;

4. Symptom scores will be determined with the Nasal Obstruction Symptom Evaluation (NOSE) Scale;

5. Cost-effectiveness.

Study description

Background summary

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.

Study objective

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.

Study design

1. Baseline;

2. 3 months;

3. 6 months;

4. 12 months;

5. 24 months.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-02-2013
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	NL3698
NTR-old	NTR3868
Other	WHO: The Universal Trial Number (UTN) : U1111-1139-7254
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A