

Effectiveness of Septoplasty

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON38891

Source

ToetsingOnline

Brief title

Effectiveness of Septoplasty

Condition

- Upper respiratory tract disorders (excl infections)
- Respiratory tract therapeutic procedures

Synonym

crooked nose, nasal septal deviation

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

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

Intervention

Keyword: effectiveness, septoplasty, septum, trial

Outcome measures

Primary outcome

health related quality of life

Secondary outcome

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

Study description

Background summary

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.

Study 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.

Intervention

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

Study burden and risks

Participation to this trial does not have any extra risks for the patient. Patients would have this surgery prescribed anyway by their ENT doctor, while the beneficiary effect is not yet been proven. The 4 phase rhinomanometry is a

non invasive method which measures the nose passage (participant needs to breathe in and out through the nose with a mask on the nose). Filling out questionnaires en diaries is not considered as a burden. The participant pays in total 4 extra visits to the hospital.

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

adult patient (aged > 17 years) selected for septoplasty because of a septal deviation causing nasal obstruction

Exclusion criteria

Patients selected for septoplasty due to a septal perforation, patients with previous septal surgery as well as patients who undergo a septoplasty as part of a cosmetic rhinoplasty procedure will be excluded.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO	
Date:	14-05-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	03-04-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	26-06-2014

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-10-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-11-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL43509.091.13
Other	NTR TC3868