Clinical benefit and cost effectiveness of endoscopic sinus surgery (ESS) in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP)

No registrations found.

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

Summary

ID

NL-OMON24555

Source
NTR

Brief title
Clinical Benefit of endoscopic sinus surgery in nasal polyps

Health condition

Rhinosinusitis (rhinosinusistis)
surgery (chirurgie)
drug treatment (medicamenteuze behandeling)
nasal polyps (neuspoliepen)

Sponsors and support

Primary sponsor: Amsterdam Medical Centre, Department of Ear-, Nose- and Throat (ENT)
Source(s) of monetary or material Support: ZonMw
European Rhinologic Society
Amsterdam Medical Centre, Department of Ear-, Nose and Throat (ENT)

Intervention

Outcome measures

Primary outcome

The primary clinical endpoint is HRQol in CRSwNP patients, measured by the SNOT-22 at 12 months follow-up. HRQol is a
frequently used clinical endpoint in CRS clinical trials.

Secondary outcome

The effectiveness of ESS in addition to drug treatment as compared to drug treatment alone in adults with CRSwNP in the short
(3-6 months) and long (12 - 24 months) term, in terms of:

• Generic HRQoL (EQ-5D-5L)

• Disease specific HRQoL and symptoms (SNOT-22)

• Endoscopic assessment of the nose

(Endoscopic assessment of the nasal cavity, graded using the Lildholt scale) Endoscopic assessment of the nose (Lund-Kennedy endoscopy scores and Modified Lund Mackay Postoperative
Endoscopy Score)

• Olfactory function (Sniffin Sticks)

• Nasal obstruction (PNIF)

• Daily records cards (DRC) will be provided 2 weeks before until 2 weeks after a visit to the clinic to record daily symptoms, medication use, adverse events, healthcare resource use and related health care costs

• CRS disease control (EPOS CRS control test, NOSE test)

• Asthma control in the subgroup of patients with asthma (Asthma Control Test)

• Symptomatic exacerbations requiring further treatment including ESS identified using diaries and medical notes

• Adverse effects of drug and surgical treatment and readmissions identified using diaries and medical notes

• Healthcare resource use and related health care costs including patient time and travel costs, out-of-pocket expenditure,
time off education, work and usual activities using repeated questionnaires and diaries (DRC)

Study description

Background summary

Given its prevalence (11% in Europe, 14,6% in the Netherlands) and the significant negative effect on quality of life, the diagnosis and treatment of chronic rhinosinusitis (CRS) is associated with a significant medical resource use and societal economic burden. CRS has been shown to have a negative impact on most aspects of Health related Quality of Life and has a greater impact on HRQoL than chronic heart failure, angina, diabetes or back pain. CRS is the most common reason for surgery (ESS) in adult patients in the otorhinolaryngological practice with around 18,000 ESS performed in The Netherlands yearly (2010 data stichting hospital data (DHD)). CRS can be divided into the more serious disease CRS with nasal polyps (CRSwNP) (prevalence 1-4%) and CRS without nasal polyps (CRSsNP). Around 70% of the ESS is done in patients with CRSwNP. Surgery requires anaesthesia and convalescence and has a small but relevant risk of serious (intracranial) complications. At present it is unknown whether ESS added to drug treatment offers significant benefits over drug treatment alone. The objective of this open multi-centre randomized trial is to investigate whether these two regular used strategies in adults with CRSwNP differ in improvement in health related quality of life (SNOT-22, EQ-5D-5L) at 12 months follow-up (primary outcome). Furthermore both strategies will be compared with respect to cost-effectiveness. Based on the primary outcome measurement, a sample size of 238 patients will have 90% power to detect a difference in means of 8.9, standard devitation 20.0 using a 0.05 two-sided significance level. Eligible patients will be randomized to a. ESS within 6 weeks in addition to drug treatment, or b. drug treatment alone. We will need 2 months start-up, 18 months of inclusion and 24 months follow-up.

Study objective

Current practice variance in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) is not efficient. Endoscopic sinus surgery (ESS) is the most common ENT operation in adults in the Netherlands. The
objective of the present study is to investigate the clinical effectiveness and cost--effectiveness of two regular
used strategies (“ESS in addition to drug treatment (usual care)” versus “drug treatment alone”) in adults with
CRSwNP with regard to improvement in health related quality of life (HRQoL: SNOT-22, EQ--5D-5L) at 12 months follow-up.

Study design

N/A

Intervention

Eligible patients will be randomly assigned in a 1:1 ratio to one of both interventions:

1. a surgical strategy consisting of ESS in addition to drug treatment. Those assigned to the surgical strategy will be offered endoscopic sinus surgery within 6 weeks of randomization. In this study we mean by endoscopic sinus surgery the surgery as done regularly by otorhinolaryngologists in the Netherlands. We do not standardize surgery.

2. a medical strategy consisting of drug treatment alone.Those assigned to the drug treatment strategy will be seen by the otorhinolaryngologist within 6 weeks of randomization to evaluate the need for additional medical treatment. Drug treatment can be any treatment that is normally given in routine medical practice to treat CRSwNP. We do not standardize drug treatment because we want to stay closest to standard of care.
The randomization will be website-based, using block randomization and stratified by study centre.

Contacts

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Eligibility criteria

Inclusion criteria

Informed consent

Bilateral CRSwNP (nasal polyps)

Age >17 years

Indication for endoscopic sinus surgery (primary or revision) as judged by their ENT surgeon

Exclusion criteria

1. Inability to comply with study protocol

2. Septal surgery without ESS

3. Polypectomy without ethmoidectomy

4. Turbinate surgery

5. Radical surgery

6. Denker surgery/ Draf III

7. Surgery for mucokeles

8. Systemic diseases affecting the nose

(e.g., Wegener’s, granulomatosis, sarcoid, primary ciliary dyskinesia, cystic fibrosis)

9. Antrochoanal polyps (benign polyps originating from the mucosa of the maxillary sinus).

10. Inverted papilloma and malignant polyps.

11. Acute upper or lower respiratory tract infections within 2 weeks before the inclusion visit),

12. Use of systemic corticosteroids within 4 weeks before the inclusion visit

13. Need of continuous systemic corticosteroids treatment for other disease than CRSwNP

14. Systemic diseases preventing participation in the study (e.g. severe cardiovascular/pulmonary illness, malignancy, auto-immune disorders)

15. Pregnancy

16. Inability to be operated

17. Medication: B-blocker, systemic corticosteroid use, ACE-inhibitors

18. Aspirin intolerance

19. Alcohol/drug abuse

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):	01-01-2015
Enrollment:	238
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-11-2014
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	NL4707
NTR-old	NTR4978
Other	METC, ZonMw : a. NL48200.018.14, b. 837002522

Study results