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

Gepubliceerd: 27-11-2014 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON24555

Bron
Nationaal Trial Register

Verkorte titel
Clinical Benefit of endoscopic sinus surgery in nasal polyps

Aandoening

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

Ondersteuning

Primaire sponsor: Amsterdam Medical Centre, Department of Ear-, Nose- and Throat (ENT)
Overige ondersteuning: ZonMw
European Rhinologic Society
Amsterdam Medical Centre, Department of Ear-, Nose and Throat (ENT)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Otorhinolaryngology,
Room A2-234,
P.O. Box 22660
W.J. Fokkens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663789

Wetenschappelijk

Academic Medical Center (AMC), Department of Otorhinolaryngology,
Room A2-234,
P.O. Box 22660

W.J. Fokkens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663789

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Informed consent

Bilateral CRSwNP (nasal polyps)

Age >17 years

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	238
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-11-2014
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	NL4707
NTR-old	NTR4978
Ander register	METC, ZonMw : a. NL48200.018.14, b. 837002522

Resultaten