F.E.S.: FESS effectiveness Study: a multi-centre randomised controlled trial studying the effectiveness of functional endoscopic sinus surgery (FESS) in adult patients with chronic rhinosinusitis/nasal polyps unresponsive to medical therapy.

No registrations found.

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

Summary

ID

NL-OMON22233

Source
Nationaal Trial Register

Brief title
F.E.S.

Health condition

CRS: Chronische Rhinosinusitis
NP: Nasal Polyps

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome measure is a validated disease-specific quality of life questionnaire: SNOT-20.

Secondary outcome

The secondary endpoint is re-evaluation of the indication for FESS. Another secondary endpoint will be the standardised evaluation of the nasendoscopy and the CT-scan. For the efficiency assessment 2 secondary endpoints will be evaluated: days of sick-leave and a work-productivity questionnaire.

Study description

Background summary

Functional Endoscopic Sinus Surgery (FESS) is a well-accepted component of the management of chronic rhinosinusitis (CRS) with or without nasal polyps (NP). Evidence level III studies show success rates of FESS between 85-95% improvement. Eventhough FESS is often performed, 10.000/year in the Netherlands, evidence level I is lacking. The relevance of CRS/NP follows the high prevalence and the high impact on quality of life, which results in significant costs.

In a prospective, multi centre, randomised controlled trial the efficacy and cost-effectiveness of Functional Endoscopic Sinus Surgery (FESS) plus medical treatment is studied and compared to ongoing medical treatment. Patients having the common condition chronic rhinosinusitis with or without nasal polyps with its severe impact on the quality of life are eligible if they are refractory to the regular medical treatment and have an indication for FESS.

One treatment arm will receive FESS plus a standardised form of medical treatment. The control group will receive standardised medical treatment. The primary outcome measures is a validated rhinosinusitis specific quality of life questionnaire: Sinonasal Outcome test (4). A sample size of 77 in each group (154 in total) will have 80% power to detect a difference in means of 0.5 assuming that the common standard deviation is 1.1 using a two group t-test with a 0.05 two-sided significance level (4). The treatment arms will be stopped and evaluated at the time-point of 3 months. For the long-term follow-up evaluation of FESS the total duration of this study will be 1 year.

After checking the assumptions of normality and constant variance an unpaired t-test will be performed to compare the means in the 2 groups. The economic evaluation of FESS is designed as a cost-effectiveness study, with primary economic outcome expressed as cost

difference per CRS-severity-adjusted life time. Costs are distinguished in direct medical and non-medical costs, and indirect costs; they will be estimated according to current methodology and national guidelines (12). Days of sick leave and the EuroQoL questionnaires (generic health) will be used.

The trial start-up will take a half year, inclusion-period 1 year, trial duration 1 year and analysing the results another half year, which leads to a total planned study duration of 3 years.

Study objective

FESS is effective: giving significant reduction of symptoms.

The indication for FESS must be based on the symptoms of the patient and its duration, CT scan abnormalities and/or nasal endoscopic abnormalities, and a history of adequate conservative treatment.

Intervention

The intervention to be investigated is FESS: Functional Endoscopic Sinus Surgery. One treatment arm will receive FESS plus a standardised form of medical treatment. The control group will receive standardised medical treatment. The standardised medical treatment is topical steroids for mild CRS (without NP). in moderate/severe disease a long-term antibiotic is added. The therapy for NP will be corticosteroids. For mild NP a spray, for moderate disease: spray and drops, and for severe disease: oral steroids with drops. Specific details are in the protocol.

Contacts

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Eligibility criteria

Inclusion criteria

1.Males or females aged 18 years old can participate.
2.Diagnosis CRS with/without NP (definition according to EPOS)
3.Prior treatment as defined in the treatment scheme of the protocol for at least 12 weeks
4.No prior sinus surgery
5.Indication for FESS, both criteria must be met:
-RSOM-31 (add score of magnitude of questions 1,2,4,22 result > 9)
-CT score > 3 on 1 side at least, judged on a CT-scan made prior to visit 1 and made less than 4 months ago; Lund/Mackay scoring;
6. Written informed consent.

Exclusion criteria

1. Cystic fibrosis;
2. Gross immunodeficiency (congenital or acquired);
3. Congenital mucociliary problems e.g. primary ciliary dyskinesia (PCD);
4. Non-invasive fungal balls and invasive fungal disease;
5. Systemic vasculitis and granulomatous diseases;
6. Patients who have any serious or unstable concurrent disease;
7. Any structural nasal abnormalities (other than polyps or chronic sinusitis), e.g. severe nasal septum deviation;
8. Rhinosurgery during the past 6 weeks;
9. Systemic steroids 4 weeks before the study;
10. Medication affecting nasal mucosa (cyclosporine, ß-blocker, ACE inhibitors, NSAIDs, reserpine, guanethidinge, phenolomine, methyldopa, alfa-adrenoceptor antagonist and chlorpromazine);
11. Medication other than trial medication;
12. Females who are pregnant or lactating;
13. Inability to follow the instructions within this protocol or known inability to attend ALL clinical visits within the intervals stated.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2006
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-01-2006
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	NL515
NTR-old	NTR558
Other	: N/A
ISRCTN	ISRCTN87577685

Study results

Summary results
N/A