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FES: 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

Submission date
14/02/2006

Recruitment status
No longer recruiting

Registration date
14/02/2006

Overall study status
Completed

Last Edited
14/08/2009

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.fess.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR558

Study information

Scientific Title

Acronym
FES

Study objectives
FESS is effective: giving significant reduction of symptoms.
The indication for FESS must be based on the symptoms of the patient and its duration, computed tomography (CT) scan abnormalities and/or nasal endoscopic abnormalities, and a history of adequate conservative treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic rhinosinusitis (CRS), nasal polyps (NP)

Interventions
The intervention to be investigated is Functional Endoscopic Sinus Surgery (FESS). 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 therapy is a spray, for moderate disease therapy is a spray and drops, and for severe disease therapy is oral steroids with drops. Specific details are in the protocol.

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
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.

Overall study start date
01/01/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Males or females aged 18 years old can participate
2. Diagnosis CRS with/without NP (definition according to the European Position Paper on Rhinosinusitis and Nasal Polyposis [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:
5.1. RSOM-31 (add score of magnitude of questions 1, 2, 4, 22 result >9)
5.2. 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

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key 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 (cyclosporin, ß-blocker, ACE inhibitors, non-steroidal anti-inflammatory drugs [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

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center, Amsterdam
Almere
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
ENT Department
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration