

# 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

<b>Submission date</b> 14/02/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/08/2009	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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,  $\beta$ -blocker, ACE inhibitors, non-steroidal anti-inflammatory drugs [NSAIDs], reserpine, guanethidine, phenolamine, methyldopa,  $\alpha$ -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)

**ROR**

<https://ror.org/03t4gr691>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Academic Medical Centre (AMC) (Netherlands)

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes