# Management of Acute Rhinosinusitis: Implementation of Guidelines in General Practice

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To compare the EPOS guideline with the free choice treatment of the GP for acute rhinosinusitis in general practice.

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| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Respiratory tract infections |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36879

**Source**
ToetsingOnline

**Brief title**
MARS study

### Condition

- Respiratory tract infections

**Synonym**
common cold, Rhinosinusitis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Hartington Pharmaceutical, S.L.,Hartington Pharmaceutical;S.L. (kleine unrestricted grant)

## Intervention

**Keyword:** (Acute) Rhinosinusitis, Common cold, EPOS guidelines, General practitioners

## Outcome measures

### Primary outcome

Primary endpoint will be the time to symptom resolution compatible with normal daily activities based on major symptom score (MSS, as also defined by Meltzer). MSS is the sum of rhinorrhea, postnasal drip, nasal congestion/stuffiness, sinus headache and facial pain/pressure/tenderness on palpitation over the paranasal sinuses. With this score patients can report the severity of the symptoms of rhinosinusitis are to them on a 0 to 3 scale.
At inclusion each patient will be provided with an electronic online diary and will be asked to record symptoms twice daily in the first 14 days and once daily from day 15 untill day 21, using the MSS.

### Secondary outcome

- Mean MSS after treatment of ARS
- Therapeutic response: using the Global Rating of Response to treatment on a 7-point scale as follows: -3 severely worse; -2 moderately worse; -1 mildly worse; 0 no change; 1 mild relief; 2 moderate relief; 3 complete relief
- Change in QoL (Quality of Life): RhinoQOL items (14 questions) to determine patient's quality of life on day 1, 7 and 21
- Adverse events: patients will record adverse events or unusual healthrelated events on the electronic diary daily.

# Study description

### Background summary

Rhinosinusitis is one of the most common reasons for a visit in general practice and can be of great influence on a person*s quality of life. Recently a taskforce endorsed by the European Academy of Allergology and Clinical Immunology (EEACI) and the European Respiratory Society (ERS) has come up with clear uni-interpretable definitons of rhinosinusitis (RS) which can be used for epidemiological and clinical research (The European Position Paper of Rhinosinusitis and Nasal Polyps, EPOS). This is the first combined guideline for primary care and secondary medical care. Acute rhinosinusitis (ARS) is defined as an acute onset of symptoms lasting less than 12 weeks with complete resolution and can be sub-divided into common cold (acute viral rhinosinusitis) defined by duration of symptoms of less than 10 days, and acute non-viral rhinosinusitis defined by an increase of symptoms after 5 days or persistent symptoms after 10 days with less than 12 weeks duration.
Current treatment for ARS commonly involves antibiotic therapy, although the use of antibiotics in the management of ARS is controversial. Recently mometasone furoate (MF) has been shown to be significantly superior to placebo and amoxicillin at improving symptom score and on health-related quality of life in the treatment of mild to moderate ARS. For that reason the EPOS guidelines advise nasal corticosteroids in these patient categories, reserving antibiotics for patients with severe disease characterized by high fever or severe pain. General practitioners (GPs) in the Netherlands only consider to prescribe nasal corticosteroids in 19,4% in mild ARS (2,6% of them considering nasal corticosteroids to be their first choice treatment) and in 37,3% in moderate ARS (21,7% of them considering nasal corticosteroids to be their first choice treatment). Nasal corticosteroids are only advised in case of an abnormal course of rhinosinusitis in de guideline of the Dutch College of General Practice (DCGP)
In 2003 Bousquet published a study on the implementation of the (Allergic Rhinitis and its Impact on Asthma) ARIA guidelines in allergic rhinitis. In this study, general practitioners* (GP*s) patients with seasonal allergic rhinitis managed as presribed in the ARIA guidelines did significantly better than the patients receiving the preferred management of the GP.Recently the same study design was repeated in specialists.

### Study objective

To compare the EPOS guideline with the free choice treatment of the GP for acute rhinosinusitis in general practice.

### Study design

In this study we plan to use a similar method as Bousquet did in 2003 to assess whether following the EPOS guidelines in the management of acute rhinosinusitis is better than the free-choice treatment of the GP (following the guidelines of de Dutch College of General Practitioners (DCGP)). In a randomized study we will compare two therapeutic strategies in acute rhinosinusitis during a management and follow-up period of 3-weeks. Each GP will recruit the first 10 patients to present with acute rhinosinusitis. GP and their patients will be randomized into two subgroups. Physicians in the first group will enroll patients and follow a simple strategy based on the EPOS guidelines. Note: patients will only be included if they comply with the EPOS definition of acute rhinosinusitis. Patient with a common cold according to the flowscheme will receive nasodren and analgetics (paracetamol). Patients with persistent or increasing disease after 5 days will receive intranasal corticosteroids. Only patients with severe acute rhinosinusitis will receive additional antibiotics. Physicians from the second group (free-choice Group) will enroll patients whom they treat as they usually do in normal practice, following the DCPG guideline. Symptomatic relief (decongestants, pain relief) is allowed during the whole trial in both groups as they will not influence the course of the disease (in case GP prescribes decongestants and nasodren, they should be administered with a gap of 3 hours).
Primary endpoint will be the time to symptom resolution compatible with normal daily activities based on major symptom score (MSS, as also defined by Meltzer). MSS is the sum of rhinorrhea, postnasal drip, nasal congestion/stuffiness, sinus headache and facial pain/pressure/tenderness on palpitation over the paranasal sinuses. Other points are quality of life (QoL), using a validated questionnaire on rhinosinusitis (RhinoQOL), therapeutic response and adverse events.

### Intervention

Acute rhinosinusitis will be treated according to the GP choice in one group. The other group will be treated following de EPOS guidlines.

### Study burden and risks

Both treatments are guidelines for acute rhinosinusitis, so both group will recieve treatment. This results in a low risk for the participants. There is minimal burden, participants only have to answer questionnaires.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

males and females aged >18 years
Availability of an internetconnection
written informed consent

## Exclusion criteria

1. Symptoms or signs of extrasinus complications
2. Use of topical antimicrobial agents in the nose, intranasal corticosteroids, systemic steroids, or immunosuppressive drugs during the previous 30 days
3. Use of oral antibiotics during the previous 30 days
4. Significant anatomic abnormalities affecting nasal function
5. Nasal surgery during the previous three months
6. Subjects who have any serious or unstable concurrent disease
7. Pregnant or lactating women
8. Subjects with chronic rhinosinusitis (symptoms for longer than 12 weeks), nasal polyps or a history of nasal polyps
9. Inability to follow the instructions within this protocol

10. Contra-indications for studymedication

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 1000 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Doxycycline |
| Generic name: | Doxycycline |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Fluticasone nosespray |
| Generic name: | Fluticasonepropionate |
| Registration: | Yes - NL outside intended use |
| Product type: | Medicine |
| Brand name: | paracetamol |
| Generic name: | paracetamol |
| Registration: | Yes - NL intended use |

# Ethics review

Not approved

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| Date: | 18-12-2012 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 |
|---|---|
| EudraCT | EUCTR2012-003734-16-NL |
| CCMO | NL41695.018.12 |