PRET-study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26931

Source
NTR

Brief title
Prednisolone Rhinosinusitis Efficacy Trial (PRET) - study

Health condition

Rhinosinusitis-like symptoms
Rhinosinusitis
Sinusitis

Rhinosinusitis-achtige klachten
Rhinosinusitis
Sinusitis

Sponsors and support

Primary sponsor: Julius Center for Health Sciences and Primary Care, UMC Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Resolution of facial pain at day 7

Secondary outcome

- Resumption of daily activities (school/work)

- Health related quality of life

- Cost-effectiveness

Study description

Background summary

Rationale:

"Rhinosinusitis-like symptoms" (RS) are often interpreted by general practitioners in daily practice as a bacterial infection. Therefore, antibiotics are still prescribed in approximately 70-90%, despite most RCTs with antibiotics failed to show an overall beneficial clinical effect. Nowadays, there is a strong tendency among experts to consider RS more as an inflammatory disorder. As a consequence, anti-inflammatory agents might reduce inflammation and enhance clearance of the sinuses. Available evidence of the use of steroids is however still conflicting.

Objective:

To assess the effects of a 7-day course of 30 mg prednisolone daily in addition to usual care (symptomatic) treatment in adults with RS.

Study design:

Double-blind placebo controlled randomized clinical trial.

Study population.

200 patients (¡Ý 18 yrs) with RS for ¡Ý 5 days.

Exclusion: ¡Ý 2 episodes of RS in the previous 12 months and chronic use of (intranasal) corticosteroids.

Intervention:

All patients will receive ¡®usual care¡¯ (xylomethazoline, paracetamol, steam therapy). Patients will be randomly allocated to a daily dose of either prednisolone 30 mg during 7 days or placebo.

Main endpoints:

Primary endpoint: resolution of facial pain at day 7.

Secondary endpoints: resumption of daily activities (school/work), health related quality of life and cost-effectiveness.

Statistical analysis:

Intention-to-treat analysis. Difference between groups: chi-square test. Unexpected differences in potential confounders: multiple regression analysis. Survival analysis: Kaplan-Meyer curves, log-rank statistics and hazard ratios.

Study objective

There is an ongoing discussion on the aetiology of rhinosinusitis-like symptoms (RS). Till recent years, the point of view was to consider RS as a bacterial infection to be treated with antiobiotics. However, most randomized placebo controlled trials (RCTs) in RS patients failed to show an overall beneficial effect. Nowadays, there is a strong tendency among experts to consider RS more an inflammatory disorder. As a consequence, anti-inflammatory agents might reduce inflammation and enhance clearances of the sinuses.

Study design

CFR: visit day 1

CRF: visit day 14

Diary day 1-14: subjects will record symptoms, use of medication, absenteeism from school/work during 14 days

CRF GP after 8 weeks (follow-up period):

GP records all subjects' GP contacts

Survey (telephone) at 8 weeks:
subjects are asked to complete a (telephone) survey at the end of the study period performed by the coordinating investigator.

Intervention

All patients receive usual care (symptomatic) treatment: xylomethazoline 0.1% nasal spray, paracetamol, steam therapy).

Patients will be randomly allocated to a daily dose of either prednisolone 30 mg during 7 days or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with RS for at least 5 days

2. Age > 18 years

Exclusion criteria

1. Fever > 38.5 C

2. > 2 episodes of RS in the previous 12 months

(Chronic) use of either nasal or oral corticosteroids

Contraindication for prednisolone treatment

Previous ENT surgery for malignant disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	23-04-2008
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	NL1249
NTR-old	NTR1295
Other	EudraCT number : 2008-000560-17
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A