PRET-study

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26931

Bron
NTR

Verkorte titel
Prednisolone Rhinosinusitis Efficacy Trial (PRET) - study

Aandoening

Rhinosinusitis-like symptoms
Rhinosinusitis
Sinusitis

Rhinosinusitis-achtige klachten
Rhinosinusitis
Sinusitis

Ondersteuning

Primaire sponsor: Julius Center for Health Sciences and Primary Care, UMC Utrecht
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Resolution of facial pain at day 7

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with RS for at least 5 days

2. Age > 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2008
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-04-2008

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1249
NTR-old	NTR1295
Ander register	EudraCT number : 2008-000560-17
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A