Prednisolone Rhinosinusitis Efficacy Trial (PRET) study

Published: 11-07-2008
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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.

Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON33569

Source
ToetsingOnline

Brief title
PRET study

Condition

- Viral infectious disorders

Synonym
rhinosinusitis, sinusitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Prednisolone, Primary care, Rhinosinusitis, Treatment

Outcome measures

Primary outcome

Resolution of facial pain at day 7.

Secondary outcome

Resumption of daily activities (school/work), health related quality of life

and cost-effectiveness.

Study description

Background summary

Rhinosinusitis-like symptoms (RS) is an important medical entity in general practice, with an incidence of approximately 25 per 1000 patients per year. Generally RS is a self-limiting disease lasting one to four weeks. There is an ongoing discussion on the aetiology of RS. Till recent years, the point of view was to consider RS as a bacterial infection to be treated with antibiotics, despite most randomized placebo controlled trials with antibiotics in RS patients failed to show an overall beneficial effect. Therefore, there is nowadays a strong tendency among physicians, as well as researchers, that RS should be regarded more as an inflammatory than an infectious disease entity. As a consequence, guidelines of the Dutch College of General Practitioners on treatment of RS recommend symptomatic treatment with analgesics and decongestive nosedrops (xylomethazoline) during the first two weeks. Despite pain reduction and decongestive therapy, this period is long and inconvenient for most patients as RS is often accompanied with insomnia, loss of appetite, feeling unwell and absence of work/school. This, together with patient expectation in favour for antibiotics, is probably the main reason for high prescription rates of antibiotics in patients during episodes of RS in general practice. Antibiotics are namely prescribed in minimally 70% of these episodes, leading to considerable costs and unwanted side-effects, besides, most notably inducing bacterial resistance. In line with the pathophysiological consideration mentioned above - to regard RS rather as an inflammatory disease - it has been hypothesized to treat patients with ongoing RS with intranasal and/or systemic corticosteroids to reduce inflammation and enhance clearance of the sinuses. Till date no clear scientific evidence is available to support (or reject) this hypothesis; the evidence on use of INCS in RS is conflicting, while there is limited evidence that short course of systemic steroids (as additive therapy to antibiotics) is beneficial in patients with RS. Whether a short course of oral steroids, as a monotherapy, is cost-effective in the large

population of patients with RS is unknown.

Study 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.

Intervention

A 7 day course of 30 mg prednisolone per os once daily in addition to xylomethazoline nasal spray q8h for 7 days (usual care).

Study burden and risks

A short course of systemic prednisolone (30 mg prednisolone q24h during 7 days) has been successfully prescribed in inflammatory disease entities like exacerbations of asthma and COPD, diminishing signs and symptoms of the lower airways, and as a consequence accelerate recovery significantly. This treatment may shorten the duration of symptoms in RS as well. As a result, this will diminish school/work absenteeism, use of analgesics and antibiotics (as well as its side-effects) and lead to a decrease in sleeping disorders. In addition, the incidence of secondary bacterial infections (now about 5%) might be reduced. Furthermore, the potential benefit of prednisolone treatment could result in a massive reduction of medical costs.
Importantly, steroid use may confer side-effects, although mainly among patients receiving these drugs for prolonged periods. A literature search was performed to identify potential side-effects of a short course of prednisolone therapy. None of these studies did show any information to be considered relevant and did not lead to discontinuation of study interventions. However, side-effects could also occur during a one week treatment period. As a consequence, these will be closely monitored. All contacts of included patients will be monitored for a follow up of eight weeks. The side-effects of prednisolone will be determined and balanced against the potential benefits.

The burden associated with participation includes two GP visits (day 1 and day 14). The GP will perform a standardised history taking and physical exam during these visitis. Besides, the subjects are asked to complete a diary during 14 days (general questions, daily symptomscore, questionnaire at day 14) and to complete a telephone questionnaire at the end of the study period of eight weeks.

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

Patients with rhinosinusitis-like symptoms - according to the criteria of the guidelines of the Dutch College of General Practitioners - for at least 5 days;Age > 18 years

Exclusion criteria

Fever > 38.5°C (measured by GP);> 2 episodes of RS in the previous 12 months;use of either nasal or oral corticosteroids in the previous 4 weeks;Contraindication for prednisolone treatment;Pregnancy;Previous ENT surgery for malignant disease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-12-2008
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Prednisolone
Generic name:	Prednisolone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-07-2008
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	16-09-2008
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	21-10-2008
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-07-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-10-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-10-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-11-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-11-2009
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2008-000560-17-NL
CCMO	NL21764.041.08

Study results

Date completed: 28-04-2011

Results posted: 19-09-2018

First publication
01-01-1900

URL result
URL
Type
ext
Naam
www.zonmw.nl
URL
Type
int
Naam
M2.3 Relevante publieke websites
URL
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Naam
M2.3 Relevante publieke websites
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