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A double blind randomised placebo-controlled trial of amoxycillin and budesonide in patients with acute rhinosinusitis in general practice

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
15/12/2008

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SEO 133

Study information

Scientific Title

Study objectives
Antibiotics are widely prescribed for acute symptomatic rhinosinusitis in general practice despite marginal evidence for their benefit. Other potential anti-inflammatory agents may help, in particular topical steroids are under researched.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Ear, nose and throat diseases: Ear, nose and throat diseases

Interventions
1. Amoxycillin tablets 500 mg twice daily for 10 days versus placebo
2. Budesonide nasal spray 200 µg each nostril once daily for 10 days versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amoxycillin, budesonide

Primary outcome measure
The percentage with diary recorded complete resolution of all symptoms (cured) at 14 days.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

Completion date
31/08/2004

Eligibility

Key inclusion criteria
Patients 16 years or over attending the GP for acute rhinosinusitis, who agree to be randomised.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Added December 2008: 240

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2001

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Medical Care
Southampton

United Kingdom
SO16 5ST

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	05/12/2007		Yes	No