

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

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/12/2008	Condition category Ear, Nose and Throat	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Double blind randomised placebo-controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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**

United Kingdom

England

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)

Funder(s)**Funder type**

Government

Funder Name

NHS Executive South East (UK)

Results and Publications

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