

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/12/2008	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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. Amoxicillin 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)

Amoxicillin, 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