

Impact of azithromycin and clarithromycin therapy on pharyngeal carriage of macrolide-resistant streptococci among healthy volunteers: a randomised, double-blind, placebo-controlled trial

Submission date
18/07/2006

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
04/09/2006

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
25/09/2009

Condition category
Infections and Infestations

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

Study information

Scientific Title

Study objectives

To assess the direct impact of antibiotic use at the individual level.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Medical Ethics Committee at the University Hospital of Antwerp, Belgium (reference: 2/29/106).

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pharyngeal carriage of macrolide-resistant streptococci

Interventions

Volunteers were administered either azithromycin (500 mg) once daily for three days, clarithromycin (500 mg) twice daily for seven days, or a placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Azithromycin and clarithromycin

Primary outcome(s)

Changes in proportions of Macrolide-Resistant Streptococcal (MRS) carriage in the oropharynx.

Key secondary outcome(s)

Variations in the oropharyngeal carriage of macrolide-resistance genes due to macrolide exposure.

Completion date

30/10/2003

Eligibility**Key inclusion criteria**

Healthy adults (18 years of age or older, non-pregnant, free of any respiratory tract infection and not having been administered any antibiotic at least in the past three months) were recruited after informed consent.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Less than 18 years
2. Having a respiratory infection
3. Having taken an antibiotic course in the previous three months

Date of first enrolment

01/07/2002

Date of final enrolment

30/10/2003

Locations**Countries of recruitment**

Belgium

Study participating centre

Dept. of Medical Microbiology

Antwerp

Belgium

B-2610

Sponsor information**Organisation**

Abbott Pharmaceuticals (Belgium)

ROR

<https://ror.org/04x0p4p48>

Funder(s)

Funder type

Industry

Funder Name

Abbott Pharmaceuticals (Belgium)

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	10/02/2007		Yes	No