

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/09/2009	Condition category Infections and Infestations	<input type="checkbox"/> 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

N/A

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).

Study design

Randomised double-blind placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/07/2002

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

203

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)

Sponsor details

ABBOTT s.a./n.v.

Parc Scientifique

Rue du Bosquet 2

Ottignies

Louvain-La-Neuve

Belgium

B-1348

Sponsor type

Industry

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Abbott Pharmaceuticals (Belgium)

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	10/02/2007		Yes	No