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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	Recruitment status	[_] Prospectively registered
18/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2009	Infections and Infestations	

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