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Sumamed Phase IV Study: Treatment of respiratory tract infections in adults and children

Submission date	Recruitment status	[_] Prospectively registered
13/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/09/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2015	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
SUM-2006/01-INT

Study information

Scientific Title
Safety and efficacy of Sumamed® therapy in the treatment of respiratory tract infections in adults and children: international, multicentre, non-comparative study

Acronym
SuPoRTI

Study objectives
In the last twenty years resistance of bacteria causing respiratory tract infections increased, but reports on how that affects the results of the treatment are scarce and controversial. This phase IV study is designed to capture real-world efficacy and safety data of Sumamed® (azithromycin) therapy in the population of 2,000 patients, adults and children with bacterial respiratory tract infections. The conditions will include the following:
1. Acute pharyngitis/tonsillitis
2. Acute sinusitis
3. Acute otitis media
4. Acute exacerbation of chronic bronchitis
5. Community acquired pneumonia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approvals have been obtained for the lead centres in the following countries:
1. Bosnia and Herzegovina: Federal Ethics Committee (Federalno ministarstvo zdravstva - Federalno eticko povjerenstvo). Date of approval: 27/02/2008
2. Croatia: Central Ethics Committee for Medicines and Medical Products (Sredinje eticko povjerenstvo za lijekove i medicinske proizvode Ksaverska cesta 4). Date of approval: 31/03/2008
3. Macedonia: Medical Ethics Committee, Skopje (Eticka komisija za medicinski istrauvanja Medicinski fakultet 1000 Skopje). Date of approval: 17/01/2008
4. Slovenia: Ethics Committee, Institute of Clinical Neurophysiology (Intitut za klinicno nevrofiziologijo Republika komisija za medicinsko etiko). Date of approval: 07/04/2008

Approvals are pending for the lead centres in the following countries:
5. Hungary: Central Ethics Committee (Egészségügyi Tudományos Tanács Klinikai Farmakológiai Etikai Bizottság [ETT KFEB])
6. Poland: Ethics Committee, Medical University of Lódz (Komisja Bioetyczna przy Uniwersytecie Medycznym, Uniwersytet Medyczny w Lodzi)
7. Romania: National Ethics Committee
8. Russia: Central Ethics Committee attached to the Federal Service on Surveillance in Healthcare and Social Development
9. Ukraine: Central Ethics Committee attached to the Ministry of Health

Information on ethics approval to be confirmed for lead centres in the following countries:
10. Belarus
11. Czech Republic
12. Kazahstan

Study design

Phase IV observational open non-comparative international multicentre study

Primary study design
Observational

Secondary study design

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Bacterial respiratory tract infections

Interventions
Adults and children >=45 kg: azithromycin (oral) 500 mg in the form of tablets once daily for 3 days
Children: azithromycin 10 mg/kg, in the form of powder for oral suspension, once daily for 3 days

Total duration of follow-up for each participant:
1. For acute pharyngitis/ tonsillitis, acute sinusitis and acute otitis media patients: 10 - 12 days
2. For acute exacerbation of chronic bronchitis and community acquired pneumonia patients: 28 - 32 days

Acute pharyngitis/ tonsillitis, acute sinusitis and acute otitis media patients will visit investigators 3 times (visits 1, 2 and 3). Acute exacerbation of chronic bronchitis and community acquired pneumonia patients will visit investigators 4 times (visits 1, 2, 3 and 4).

Timepoints:
Visit 1 will take place on Day 1
Visit 2 will take place on Day 4
Visit 3 will take place between Day 10 - 12
Visit 4 will take place between Day 28 - 32

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Azithromycin

Primary outcome measure

Clinical efficacy of the treatment defined as cure, improvement, failure or not-evaluable, assessed at visits 3 and 4.

Timepoints:
Visit 1 will take place on Day 1
Visit 2 will take place on Day 4
Visit 3 will take place between Day 10 - 12
Visit 4 will take place between Day 28 - 32

Secondary outcome measures
Tolerability, assessed through adverse events recorded at visits 2, 3 and 4. Tolerability will be presented as frequencies, percentages and 95% confidence intervals. Results will be presented for the whole group of patients and further stratified according to the clinical diagnosis.

Timepoints:
Visit 1 will take place on Day 1
Visit 2 will take place on Day 4
Visit 3 will take place between Day 10 - 12
Visit 4 will take place between Day 28 - 32

Overall study start date
16/06/2008

Completion date
15/06/2009

Eligibility

Key inclusion criteria
1. Male or female out-patients, no age limits
2. Acute onset of disease indicated by presence of fever (>37°C)
3. Presence of at least 2 specific clinical signs and symptoms
4. Signed informed consent (for minors, parent or legal guardian written consent needs to be obtained)

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
2,000

Key exclusion criteria
1. Hypersensitivity to macrolides
2. Treatment with any antibiotic within 14 days prior to enrolment

3. Participation in any clinical study within 4 weeks prior to enrolment
4. Prior enrolment in this study

Date of first enrolment
16/06/2008

Date of final enrolment
15/06/2009

Locations

Countries of recruitment
Belarus

Bosnia and Herzegovina

Croatia

Czech Republic

Hungary

Kazakhstan

North Macedonia

Poland

Romania

Russian Federation

Slovenia

Ukraine

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
PLIVA Hrvatska d.o.o. (Croatia)

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	01/06/2015		Yes	No