

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

Submission date 13/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/09/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/10/2015	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Tea Andabaka

Contact details
Ulica grada Vukovara
Zagreb
Croatia
10000
+385 (0)1 6120 717
Tea.Andabaka@pliva.com

Additional identifiers

Protocol serial number
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 Łódź (Komisja Bioetyczna przy Uniwersytecie Medycznym, Uniwersytet Medyczny w Łodzi)
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. Kazakhstan

Study design

Phase IV observational open non-comparative international multicentre study

Primary study design

Observational

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

All

Sex

All

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

Ulica grada Vukovara

Zagreb

Croatia

10000

Sponsor information

Organisation

PLIVA Hrvatska d.o.o (Croatia)

ROR

<https://ror.org/026t6sy78>

Funder(s)

Funder type

Industry

Funder Name

PLIVA Hrvatska d.o.o. (Croatia)

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	01/06/2015		Yes	No