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# Treatment of nasal inflammation in children using azithromycin alone or combined with lactulose.

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 20/02/2019 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 22/02/2019 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 21/02/2019 | Respiratory | [ ] Record updated in last year |

## Plain English summary of protocol

Background and aims:
Antibiotics are necessary to fight infections especially in children. Unfortunately antibiotics do not only kill bad bacteria – but also affect commensal flora (beneficial bacteria), important to good health. An effect of antibiotics, is depletion of commensal flora and a loss of this protective barrier, that leaves them exposed to a vast variety of diseases.
This study researches if commensal bacteria can benefit during the administration of antibiotics when a prebiotic (Lactulose) is given during treatment. Lactulose, a flora nourishment is expected to allow commensal flora to survive the treatment delivering a more beneficial treatment approach with less adverse effects.

Who can participate?
Children of both sexes, between 3 and 14 years of age, diagnosed with Acute Purulent Sinusitis were included. All subjects had provided written informed consent (signed by parent/guardian) and have agreed not to take other prebiotics, probiotics, synbiotics, and/or sorbents during the course of the study.

What does the study involve?
Patients with diagnosis of Acute Purulent Sinusitis have been treated with antibiotic. Group 1 - with azithromycin plus lactulose (food for beneficial bacteria), one dose a day during three days; Group 2 – with azithromycin, one dose a day during three days. Patients provided stool before and after the treatment, and the stool was analysed on composition of beneficial or pathogenic bacteria.

What are the possible benefits and risks of participating?
Benefits were free treatment, even in the case of leaving/dropping out of the study and contribution to research.
Risks were expected possible adverse events, common and uncommon for the used antibiotic.

Where is the study run from?
This study run only in a single centre in Moscow and took place in Clinical Center 1, Children's City Polyclinic No. 133 of the Department of Health of Moscow.

When is the study starting and how long is it expected to run for?
Study had started on 21st of April, 2015 and ended on 25th of January, 2016.

Who is funding the study?
MC Development, Russia.

Who is the main contact?
Dr Christos Shammas, c.shammas@avvapharma.com

# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### Protocol serial number
ECOMED-11/2014

# Study information

### Scientific Title
An open, randomized comparative study of the efficacy and safety of using Ecomed (powder for oral suspension, containing azithromycin 100mg/5ml and lactulose 200mg/5ml, manufactured by JSC AVVA RUS, Russia) compared with Sumamed (powder for suspension, containing azithromycin 100mg/5ml, by Pliva Hrvatska doo, Croatia) in children with rhinosinusitis.

### Acronym
ECOMED

### Study objectives

Comparative evaluation of the clinical efficacy of Ecomed and Sumamed in children with rhinosinusitis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 19/01/2015, Local Committee for Research Ethics, (55 Smolnaya str. 125445, Moscow, Russia; +7 (495) 456-32-03; dgp133medved@yandex.ru), ref: GBUZ “DGP No. 133 DZM”

## Primary study design
Interventional

## Study design
An open, randomized, single-centre, comparative study of the efficacy and safety of drugs when administered to children with rhinosinusitis.

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Rhinosinusitis in children

## Interventions
Dosage regimens:
Ecomed is a powder for suspension, containing 100mg of azithromycin/5ml and 200mg of lactulose/5ml (JSC AVVA RUS, Russia);
Sumamed - suspension powder containing 100mg of azithromycin/5ml (Pliva Hrvatska doo, Republic of Croatia).
Method of administration: administration of oral suspension 1 time per day at the dose of 10mg /kg/day and 20mg/kg/day lactulose, where applicable.
Treatment duration: 3 days.
Observation period: 60 days ± 2 days.
Duration of participation of one patient in the study: 68 days (screening 3 days + 3 days of therapy and + 60±2 days observation period).

The randomization sequences were produced by web-based free randomization resource https://www.randomizer.org/. The study includes screening period, randomization period, period of treatment and monitoring (follow-up). During the research study, 4 visits are conducted: visit 1-screening; visit 2-randomization and start of treatment (baseline); visit 3-completion of treatment (day 3), visit 4- follow up (day 18) and visit 5- follow up (day 60).

## Intervention Type
Drug

## Phase
Phase IV

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

1. Ecomed (powder for oral suspension, azithromycin 100mg/5ml and lactulose 200mg/5ml, by JSC AVVA RUS, Russia) 2. Sumamed (powder for oral suspension, azithromycin 100mg/5ml, by Pliva Hrvatska doo, Croatia)

### Primary outcome(s)
The proportion of subjects with clinical improvement in the symptoms of the disease assessed by the researcher-clinician on the 4th day from the start of drug administration.
Efficacy is evaluated on the basis of the reduction and disappearance of the main subjective and objective symptoms of bacterial rhinosinusitis - the severity of difficulty in nasal breathing, the nature and severity of discharge from the nose, pain when palpating the projection of the paranasal sinuses, temperature reaction, headache, the presence and severity of general malaise.

### Key secondary outcome(s)
1. Frequency and severity of symptoms of dysbiosis in the background of the studied therapy on the 4th, 17th day after the start of therapy.
2. Proportion of patients with persistent or worsening signs of infection on the 4th day from the start of treatment, requiring replacement of antibiotic therapy.
3. Assessment of gut microbial community diversity based on the assessment of the variability of 16S genes of ribosomal RNA on the 4th, 17th day from the start of therapy and the 60th day after completion of therapy compared to the initial level.
4. Frequency of adverse events, their severity and relationship with the studied therapy.

### Completion date
25/01/2016

## Eligibility

### Key inclusion criteria
1. Outpatient patients of both sexes from 3 to 14 years.
2. Established diagnosis of Acute Purulent Sinusitis - evaluation of complaints, anamnesis, temperature, R-picture and rhinoscopy data - pus in the middle nasal passage and/or in the nasopharynx dome.
3. Ability to regularly receive the studied drugs and perform research procedures.
4. The Form of the Written Informed Consent to participate in the study is signed by one of the parents or the legal representative of the patient.
5. Informing the patients' parents that during the entire study period the patient should not take prebiotics, probiotics, synbiotics, sorbents.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
3 Years

### Upper age limit
14 Years

### Sex
All

### Key exclusion criteria
1. Intolerance to azalides, macrolides and other components of the drug.
2. Administration of antibacterial drugs, including sulfonamides, within 28 days before the start of screening.
3. Complicated course of infectious diseases of the upper and lower respiratory tract.
4. Bacterial infection of another location, requiring the administration of antibiotics.
5. Oncological disease without remission, at least for 5 years before the start of the study.
6. Epilepsy, febrile convulsions in history.
7. Impaired immunity according to anamnesis.
8. Immunodeficiency.
9. Active neoplastic process.
10. Any other serious illness or condition that could jeopardize patient safety, affect life expectancy, or hinder successful treatment or monitoring of a patient according to the protocol.
11. The reluctance of the child or his legal representatives to participate in clinical research.
12. Drug use, alcoholism, mental illness of the legal representative of the patient.
13. Participation in other clinical studies of medical drugs less than 3 months before the start of the study.

### Date of first enrolment
21/04/2015

### Date of final enrolment
18/11/2015

## Locations

### Countries of recruitment
Russian Federation

### Study participating centre
**Clinical Center 1, Children's City Polyclinic No. 133 of the Department of Health of Moscow**
Smolnaya st., 55
Moscow
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117997

## Sponsor information

### Organisation

OJSC AVVA RUS

# Funder(s)

**Funder type**
Industry

**Funder Name**
MC Development, Russia.

# Results and Publications

**Individual participant data (IPD) sharing plan**
All data generated or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**
Other