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Trial of safety, reactogenicity and pharmacokinetics of new anti-herpetic remedy Fortepren® in healthy adults

Submission date
23/02/2015

Recruitment status
No longer recruiting

Registration date
09/03/2015

Overall study status
Completed

Last Edited
09/03/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aims of this study are to run a pilot study of the safety, reactogenicity (potential to cause common adverse effects or side effects) and pharmacokinetics (what happens to the drug once it enters the body) of a new polyprenyl phosphate based anti-herpetic remedy Fortepren® in healthy adults. Fortepren® is a product obtained from fir needles polyprenols and belongs to antiviral remedies with immunomodulating activity (i.e. being able to adjust the immune response to a desired level). A set of performed pre-clinical trials has showed that the drug had no toxicity or any side effects in experiments on laboratory animals and good protective effect in the herpes virus infection model. We want to see if the same can be said for healthy adults.

Who can participate?
Healthy non-smoking adults aged 18 to 45.

What does the study involve
Participants first undergo a physical examination, where their heart rate, blood pressure and temperature at all taken. They then receive a series of Fortepren® injections at a dose of 5 mL (20 mg) administered intramuscularly. After the first injection of Fortepren® , a sample of blood is taken. Blood count, blood chemistry, urinalysis and an electrocardiogram (ECG) are all performed. 24 hours after the first injection of Fortepren® another physical examination takes place in which ECG, heart rate, blood pressure, body temperature, complete blood count, blood chemistry and urinalysis were all measured or performed. Participants are then invited to take part in the second part of the study, which takes place 9 days after the initial injection. If they agree, they are hospitalized for the next 5 days. Each participant then receives a further 5 or 6 Fortepren® injections. The total dose rate of the Fortepren® was 100-120 mg per participant. During the hospitalization, blood pressure and temperature are recorded every 3 hours (except for the interval from 23:00 to 08:00). Blood sampling for pharmacokinetics is performed before administration of the Fortepren®, then after 20 minutes, 40 minutes, 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 24 and 48 hours after injection. Safety and tolerability is assessed by collecting and analyzing

information on adverse events (AEs) and serious adverse events (SAEs) during the study period, as well as changes in the general analysis of blood and urine tests, blood chemistry and vital signs.

What are the possible benefits and risks of participating?
Some participants may experience a rise in body temperature. There are no other risks to taking part in the study.

Where is the study run from?
I.M. Sechenov First Moscow State Medical University (Russia)

When is the study starting and how long is it expected to run for?
September 2013 to November 2013

Who is funding the study?
1. Ministry of Industry and Trade of the Russian Federation
2. GamaVetFarm Ltd

Who is the main contact?
Professor Alexander Pronin

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Open phase I controlled trial of safety, reactogenicity and pharmacokinetics of new anti-herpetic remedy Fortepren® in healthy adults

Study objectives
Fortepren® is safe for healthy adults

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Board of Ethics of the Ministry of Health of the Russian Federation, 24/04/2013, ref: N 61
2. Local Ethics Committees, f 30/07/2013 ref: N 08-13

Study design
Open phase I controlled trial of safety, reactogenicity and pharmacokinetics

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Healthy adults

Interventions
The first injection of Fortepren® was performed 2 days after the screening. On the 9th day, volunteers were hospitalized for 5 days. Fortepren® at a dose of 5 mL (20 mg) was administered intramuscularly. Each volunteer underwent 5 or 6 daily injections. The total dose rate of the Fortepren® was 100-120 mg.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Fortepren® (sodium polyprenyl phosphate)

Primary outcome measure

Adverse events or changes in physical, vital, blood, and biomarker indices.

Secondary outcome measures
Evaluation the safety and tolerability of Fortepren® was carried using the following parameters:
1. Adverse events and serious adverse events (AEs and SAEs)
2. Deviations of laboratory tests (common clinical and biochemical blood analysis)

Overall study start date
09/09/2013

Completion date
08/11/2013

Eligibility

Key inclusion criteria
1. Aged 18 to 45 years old
2. Smoke less than 10 cigarettes per day
3. Verified diagnosis of "practically healthy" according to standard clinical, laboratory and instrumental methods of examination
4. Negative tests for HIV, syphilis (RW), HBs-antigen and hepatitis C (HCV RNA),
a negative pregnancy test (for female volunteers)
5. Body mass index of volunteers did not go beyond ± 15% overall weight and growth index. 6. Participants in the study complied with an adequate method of contraception during the entire time from the date of signing the informed consent form prior to the completion of participation in the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Liver or kidney disease; any other disease, which, in the opinion of the investigator, may affect the results of the study or may lead to poor health during the study
2. Clinically significant abnormalities in laboratory results
3. Course medication (including herbal products and dietary supplements) for prophylactic or therapeutic purposes in the past month
4. The presence of antibodies to HIV, hepatitis B and C
5. Consuming alcohol or narcotic drugs for 4 days prior to the study

6. Donation of blood / plasma, surgery (in the hospital) for 12 weeks prior to the study
7. Participation in other clinical studies (or study drug) within 3 months prior to the study
8. Failure to understand or follow the instructions of the Protocol
9. Receive more than 10 units of alcohol per week (1 unit of alcohol equivalent to ½ liter of beer, 200 ml of wine or 50 ml of alcohol) or anamnestic information about alcoholism, abuse of drugs
10. Smoking more than 10 cigarettes a day
11. A positive test for the presence of alcohol in the breath
12. A positive urine test for drug abuse and narcotics

Date of first enrolment
11/09/2013

Date of final enrolment
08/11/2013

Locations

Countries of recruitment
Russian Federation

Study participating centre
I.M. Sechenov First Moscow State Medical University
Moscow
Russian Federation
119991

Sponsor information

Organisation
GamaVetFarm Ltd

Sponsor details
Gamaleya st. 18
Moscow
Russian Federation
123098

Sponsor type
Industry

Website
www.gamavetfarm.com

Funder(s)

Funder type
Government

Funder Name
Ministry of Industry and Trade of the Russian Federation

Funder Name
GamaVetFarm Ltd

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository