Open-label study to compare the bioavailability of an oral tablet of GLPG1972 relative to an oral solution after single-dose intake in healthy subjects and to evaluate the effect of food on the oral tablet.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON42935

Source
ToetsingOnline

Brief title
GLPG1972 BA study.

Condition

- Joint disorders

Synonym
Arthritis.

Research involving

Human

Sponsors and support

Primary sponsor: Galapagos NV
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: GLPG1972, Osteoarthritis

Outcome measures

Primary outcome

To compare the PK of an oral tablet of GLPG1972 with an oral solution of

GLPG1972 under fasted conditions.

To evaluate the effect of food (high-fat, high calorie meal) on the PK of

GLPG1972 administered as an oral tablet.

To evaluate the safety and tolerability of single oral doses of GLPG1972.

Secondary outcome

Not applicable.

Study description

Background summary

GLPG1972 is a new investigational compound that may eventually be used for the treatment of osteoarthritis.

GLPG1972 is a potent inhibitor of human ADAMTS-5. ADAMTS-5 is an enzyme (protein) which is present in many tissues in the body, mainly in uterus, placenta and cartilage. ADAMTS-5 is responsible for the destruction of the cartilage which could lead to osteoarthritis. Blocking ADAMTS-5 could result in an inhibition of the cartilage destruction which may be a treatment for osteoarthritis.

GLPG1972 is not yet registered as a drug but has been given to humans before.

Study objective

The purpose of the study is to investigate the absorption, distribution and elimination of GLPG1972 administered as oral solution compared to GLPG1972 administered as oral tablets (this is called bioavailability). Furthermore, the effect of food on the absorption, distribution and elimination of GLPG1972 administered as oral tablets will be investigated. It will also be investigated how safe GLPG1972 is and how well GLPG1972 is tolerated.

Study design

The actual study will consist of 3 treatment periods during which the volunteers will stay in the clinical research center in Groningen for 3 days (2 nights): from the afternoon of Day -1 (1 day before administration of the study compound) to the morning of Day 2. On Day 3 they will visit the clinical research center in Groningen for a short visit. The time interval between the different treatments for each volunteer is at least 6 days.

The post-study visit will take place 7-10 days after administration of the study compound in Period 3. The appointment for the post-study visit will be made with you during the study.

The participation to the entire study, from pre-study screening until the post study visit, will be approximately 7 weeks.

In one of the three treatment periods of the study, the volunteers will receive GLPG1972 as oral solution (Treatment A). After intake of the study compound they are also required to drink an additional amount of 240 milliliters water. In the other two treatment periods, they will receive GLPG1972 as oral tablets with 240 milliliters of tap water (Treatments B and C).

Treatments A and B will be given under fasted conditions. This means that the volunteers are not allowed to eat for at least 10 hours before administration of the study compound. During fasting they are allowed to drink water with the exception of 2 hours prior to until 2 hours after administration of the study compound. Fasting will continue until 4 hours after administration of the study compound. Then they will receive a lunch. Before administration of Treatment C they will receive a standardized, non-vegetarian, high fat and high calorie breakfast. They are not allowed to eat for at least 10 hours before consumption of this high fat and high calorie breakfast. During fasting the volunteers are allowed to drink water. The breakfast will have to be finished within 20 minutes and the entire breakfast must be consumed. At 30 minutes after the start of the high fat and high calorie breakfast they will receive Treatment C. They are not allowed to eat for at least 4 hours after administration of the study compound. Then the volunteers will receive a lunch.

Intervention

Treatment A: 600 mg GLPG1972 as an oral solution after an overnight fast
Treatment B: 600 mg GLPG1972 as oral tablets (2 tablets) after an overnight fast
Treatment C: 600 mg GLPG1972 as oral tablets (2 tablets) after a high fat and high calorie breakfast

Study burden and risks

Pain, minor bleeding, bruising, possibly an infection due to blood sampling.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy male subjects
18 - 50 years of age, inclusive
BMI 18.0 - 30.0 kilograms/meter2
Body weight at least 50 kilograms
non-smoking

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 8 weeks before the start of this study or being a blood donor within 12 weeks from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2016
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-04-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015-005435-40-NL
CCMO	NL57172.056.16