An open-label, randomized crossover study to evaluate the effect of ASP1941 on the pharmacokinetics, pharmacodynamics, safety and tolerability of glimepiride in healthy subjects and vice versa.

Published: 15-12-2009
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34715

Source
ToetsingOnline

Brief title
study drug/glimepiride interaction study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 2 Diabetes Mellitus.

Research involving

Human

Sponsors and support

Primary sponsor: Astellas Pharma
Source(s) of monetary or material Support: Astellas Pharma B.V.;Leiderdorp;Nederland

Intervention

Keyword: - Glimepiride interaction study, - Type 2 Diabetes Mellitus

Outcome measures

Primary outcome

Pharmacodynamics: glucose and creatinine concentrations in urine

Pharmacokinetics: study drug and glimepiride concentrations in plasma,

pharmacokinetic parameters

Safety: adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination

Secondary outcome

nvt

Study description

Background summary

The drug to be given is a new, investigational compound that may eventually be used for the treatment of Diabetes Mellitus Type 2 (T2DM). T2DM is characterized by repeatedly increased blood glucose levels. Consequences may be that patients with T2DM are often thirsty, urinate a lot, and may have complications affecting the peripheral nerves (tingling and insensitivity in hands and feet), the blood vessels (atherosclerosis), the eyes (disease of the retina) and the kidneys (kidney failure). The new compound might help to control blood glucose levels. This new compound is still under development and as a result has not been registered as a drug.
The main objective of this study is to evaluate the effect when the new

compound is taken in combination with glimepiride. Glimepiride is a registered drug that lowers the blood glucose level and is licensed as treatment for type 2 diabetes when diet and exercise changes alone have not been successful.

Study objective

For Part A: the purpose of this part is to investigate the effect of multiple oral doses of the new study drug on how quickly and to what extent glimepiride is absorbed and eliminated from the body (this is called pharmacokinetics), if glimepiride is given as a single dose. In addition, the effect of multiple oral doses of the new study drug on the safety and tolerability of a single dose of glimepiride will be investigated.

For Part B: the purpose of this part is to investigate the effect of multiple oral doses of glimepiride on how quickly and to what extent teh study drug is absorbed and eliminated from the body (this is called pharmacokinetics), if the new study drug is given as a single dose. In addition, the effect of multiple oral doses of glimepiride on the safety and tolerability of a single dose of the new study drug will be investigated.
Also, it will be investigated if multiple oral doses of glimepiride influence the effects on the body (this is called pharmacodynamics) of the study drug.

Study design

Part A+B
This part will be of an open-label, randomized two-sequence design.

Intervention

Part A
Treatment 1: an oral dose of glimepiride on Days 1 and 8 and an oral dose of study drug once daily on Days 4-10
Treatment 2: an oral dose of glimepiride on Days 5 and 10 and an oral dose of study drug once daily on Days 1-7

Part B
Treatment 3: an oral dose of study drug on Days 1 and 6 and an oral dose of glimepiride once daily on Days 4-8
Treatment 4: an oral dose of study drug on Days 3 and 8 and an oral dose of glimepiride once daily on Days 1-5

Study burden and risks

Procedures: pain, light bleeding heamatoma, possibly an infection.

Study drug: well tolerated medication with adverse events that were of mild

intensity and short duration. More frequent reported adverse effects were headache, constipation, and frequent urination.

Glimepiride is a registered anti-diabetic drug, like all medicines, glimepiride can cause side effects although not everybody gets them. For glimepiride used in the patient population, the most commonly reported side effects are allergic reactions (including inflammation of blood vessels, often with skin rash), abnormal liver function including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure, allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun and severe hypoglycemia including loss of consciousness, seizures or coma.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Between 18 and 55 years of age
- BMI between 18.5 and 30.0 kg/m2
- Not a heavy smoker

Exclusion criteria

An important medical disorder, hepatitis B, cancer or HIV/AIDS detected during screening.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2010
Enrollment:	26
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ASP1941
Generic name:	nvt
Product type:	Medicine
Brand name:	Glimepiride

Generic name:	Glimepiride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	15-12-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-12-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-02-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-02-2010
Application type:	Amendment
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	EUCTR2009-013172-50-NL
CCMO	NL30744.056.09