A multi-center, single-dose, open-label, randomized, parallel group study to investigate the reduction of initial taspoglutide Cmax after administration of 20 mg taspoglutide 10% Sustained Release Formulation (SRF) using three modified formulations as compared to the current Phase 3 formulation in healthy volunteers.

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Primary:to assess the reduction of initial study drug Cmax after administration of 20 mg study drug 10% SRF using three modified formulations as compared to the current Phase 3 formulation in healthy volunteers.Secondary:to assess the safety and...

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

Summary

ID

NL-OMON34034

Source
ToetsingOnline

Brief title
Taspoglutide BE study in healthy volunteers

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, diabetes mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Hoffmann-La Roche
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: diabetes, Diabetes Mellitus type 2, taspoglutide

Outcome measures

Primary outcome

Pharmacokinetics

Pharmacodynamics

Safety

Tolerability

Secondary outcome

n.a.

Study description

Background summary

The drug to be given, taspoglutide, is a new, investigational compound that may eventually be used for the treatment of diabetes mellitus type 2. The study drug is still in the development phase. Current therapies for diabetes mellitus type 2 are often inefficient in controlling glucose levels because they have an

effect on only one or a few of the underlying defects. In addition, some of the antidiabetic medications are associated with undesirable side-effects. Moreover, some medications can not be used in some patients or require specific monitoring. Thus, there is a need for new antidiabetic therapies that are both more effective and better tolerated than currently available antidiabetic medications.
Taspoglutide is a novel compound, similar to a hormone in the body that is involved in regulating blood glucose levels. Previous studies with taspoglutide have already shown a sustained effect on lowering blood glucose levels. However, the formulation used until now did cause gastrointestinal complaints in some cases. The purpose of this study is to assess different formulations of taspoglutide in order to find an optimal formulation for the treatment of diabetes mellitus type 2.

Study objective

Primary:
to assess the reduction of initial study drug Cmax after administration of 20 mg study drug 10% SRF using three modified formulations as compared to the current Phase 3 formulation in healthy volunteers.

Secondary:
to assess the safety and tolerability of 20 mg study drug administered as 10% SRF using three modified formulations as compared to the current Phase 3 formulation in healthy volunteers.
to investigate the pharmacokinetics of study drug after administration of 20 mg study drug 10% SRF using three modified formulations as compared to the current Phase 3 formulation in volunteers.
to determine the effect of study drug on fasting glucose concentrations after administration of 20 mg study drug administered as 10% SRF using three modified formulations as compared to the current Phase 3 formulation in healthy volunteers.
to investigate the impact of injection speed on the pharmacokinetics of study drug.

Study design

Design:
a single-dose, open-label, randomized, parallel group study in five groups of twenty healthy subjects (at least 40% of each gender) each receiving a single subcutaneous injection of study drug, the last group (E) can be dosed only after the first four groups (A-D) have completed the first eight days of treatment

Procedures and assessments
Screening and follow up:

The screening will include a physical examination including measurement of blood pressure, pulse rate, oral temperature, anti-study drug antibodies, height, weight and waist/hip circumference, a heart trace (electrocardiogram) recording, and a number of blood and urine tests. You will also be screened for drugs of abuse, alcohol, Hepatitis B and C, and HIV (= AIDS test). In case of female participants a pregnancy test will be performed.

Observation period:
one period in clinic from -17 h up to 24 h after drug administration on Day 1 followed by ambulatory visits on Days 3, 4, 6, 8, 10, 12, 15, 17, 19, 22, 24, 26, 29, 36, 43, 50, 57*, 64*, 71*, 78* and 85* (* ambulatory visits might not be necessary in case study drug BLQ values in three consecutive plasma samples after Day 57)

Blood samples:
for pharmacodynamics of fasting plasma glucose concentrations: pre-dose, 24 h post dose and once on Days 3, 4, 6, 8, 10, 12, 15, 17, 19, 22, 24, 26, 29, 36, 43, 50, 57, 64, 71, 78* and 85* (* dependent on study drug plasma levels, see above)
for pharmacokinetics of the study drug in plasma: pre-dose, at 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 14 and 24 h post dose and once on Days 3, 4, 6, 8, 10, 12, 15, 17, 19, 22, 24, 26, 29, 36, 43, 50, 57, 64, 71, 78* and 85* (* dependent on study drug plasma levels, see above)
for anti-study drug antibodies: once on Days 22 and 50

Safety assessments:
adverse events; throughout the study; vital signs and 12-lead ECG: pre-dose and 4, 8 and 24 h post dose and once on Days 8, 15, 22, 29 , 36, 50, 64 and 78; clinical laboratory: 24 h post dose and once on Days 8, 15, 22, 29, 36, 50, 64 and 78

Bioanalysis:
analysis of study drug plasma samples using a validated method by Sponsor
analysis of anti-study drug antibodies samples using a validated method by Sponsor
analysis of fasting plasma glucose concentrations using a validated method by Sponsor

Intervention

Taspoglutide injection

Study burden and risks

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

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

Healthy male or female (Non child bearing potential)
18-65 years of age, inclusive
BMI >20 AND <<= 35 kg/m2
Non-smoker, or not more than 10 cigarettes/day for at least six months before drug administration

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 90 days from the start of the study. In case of having participated in more than 3 other drug studies (for men) /

more than 2 other drug studies (for women) in the 10 months prior to the start of this study, or when having donated more than 1.5 liters of blood (for men) / more than 1.0 liters of blood (for women) in the 10 months prior to the start of this study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2010
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Taspoglutide
Generic name:	Taspoglutide

Ethics review

Approved WMO

Date:	22-10-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	02-11-2010
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	EUCTR2010-022848-20-NL
CCMO	NL34085.056.10