A single-center, single-blind study to investigate skin response to sub-therapeutic doses of taspoglutide in GLP-1 analogue naive healthy volunteers

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The purpose of the study is to confirm the skin test results in patients based on results of the control population of healthy volunteers never exposed to taspoglutide or any product with a similar mechanism of action.

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

Summary

ID

NL-OMON34382

Source
ToetsingOnline

Brief title
Skin response to subtherapeutic doses of taspoglutide

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

To generate skin test data in healthy subjects (never exposed to taspoglutide

or any product with a similar mechanism of action) who will serve as a control

group for patients* skin test study and will allow the valid interpretation of

the test results.

Secondary outcome

na

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 in patients with diabetes mellitus type 2 have already shown a sustained effect on lowering blood glucose levels. However, the formulation used until now did cause allergic and cutaneous reactions in some patients. In order to assess

whether the observed allergic reactions were caused by the taspoglutide itself or some other component, additional skin tests will be performed in patients who previously experienced any allergic reaction. The purpose of this study is to generate skin test data in healthy subjects (never exposed to taspoglutide or any product with a similar mechanism of action) who will serve as a control group for patients* skin test study and will allow the valid interpretation of the test results. The skin prick test and intradermal test (an injection in the skin with a small amount of test substances) are established methods to investigate the potential of a compound to cause an allergic reaction as observed in previous studies. During the skin test procedures different batches of the formulation of taspoglutide used in patient studies, an extra pure taspoglutide, all in amounts that are not therapeutic, and placebo (a formulation without any active ingredient) will be tested. In addition, histamine (positive control) and a solution without active substance (negative control) will be used for reference. Everyone is expected to react to histamine and no reaction is expected from the negative control.

Study objective

The purpose of the study is to confirm the skin test results in patients based on results of the control population of healthy volunteers never exposed to taspoglutide or any product with a similar mechanism of action.

Study design

a single-center, single-blind, placebo controlled, skin testing study in six healthy volunteers to generate control group results in GLP-1 naïve healthy volunteers for validation of the patient skin test results (skin prick and intradermal test) for EP (extra pure) taspoglutide, taspoglutide used in Phase 3 studies and placebo relative to positive (histamine) and negative (buffered saline) controls

Intervention

Taspoglutide skin pricks, taspoglutide intradermal injections, positive and negative controls

Study burden and risks

Procedures: pain. Possible allergic reaction.

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 or female
Age : 18-65 yrs, inclusive
BMI : 20.0-35.0 kg/m2, inclusive

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:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2010
Enrollment:	6
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	01-12-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-12-2010
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	EUCTR2010-023582-21-NL
CCMO	NL34750.056.10