Evaluation of Insuman Implantable 400 IU/ml in patients with Type 1 diabetes treated with the Medtronic MiniMed Implantable Pump System using Insuplant 400 IU/mL

Published: 22-10-2010
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(1) To generate new clinical efficacy and safety data to support the registration of Insuman Implantable 400 IU/ml,(2) To ensure the continuation of the treatment of the patients already implanted and avoid pump explantation, up to the approval of...

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

Summary

ID

NL-OMON37980

Source
ToetsingOnline

Brief title
HUBIN_L_05335/ Insuman study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes type I

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: sanofi-aventis.

Intervention

Keyword: Insuman, Insuplant, Medtronic Minimed Implantable pump system, Type I diabetes

Outcome measures

Primary outcome

This is a safety and efficacy study of insuman.

Secondary outcome

Not applicable

Study description

Background summary

Insulin therapy by implantable insulin pumps represents a unique mode of insulin delivery. This mode of insulin administration results in lower plasma insulin levels in the peripheral venous system than those obtained by subcutaneous insulin delivery.
About 459 patients are currently treated with an implantable pump system using Insuplant 400 IU/ml. However, the production of Insuplant 400 IU/mL has been stopped and the last available Insuplant 400 IU/mL batches allow product supplies until at the latest June 2011. Given the unmet clinical need in these already implanted patients, sanofi aventis has developed an insulin formulation; tradename Insuman Implantable 400 IU/ml) suitable for use in the Medtronic Minimed implantable pump. Considering the medical need for the already implanted patients, and in light of the CHMP (The Committee for Medicinal Products for Human Use) request to provide in vivo data with Insuman Implantable, sanofi-aventis has decided to set up a clinical program.

Study objective

(1) To generate new clinical efficacy and safety data to support the registration of Insuman Implantable 400 IU/ml,
(2) To ensure the continuation of the treatment of the patients already implanted and avoid pump explantation, up to the approval of Insuman

Implantable 400 IU/ml.

Study design

The study duration will be displayed in 2 parts as follow:

Comparative phase (only French patients): 160 +/- 20 days

Open label Insuman Implantable extension phase (French and European patients): from day 160 up to the grant of Insuman implantable marketing authorization

Intervention

• Insuman Implantable 400 IU/mL
• Insuplant 400 IU/mL

Continuous Intraperitoneal insulin infusion: basal rate and boluses
• Medtronic minimed pump refill will be performed every 40 +/- 5 days

Study burden and risks

Side effects of insulin Implantable Insuman 400 IU / ml and Insuplant are similar to those of all insulins. These effects are very common (more than a patient in 10) and are mainly due to:
- hypoglycemia (low blood sugar) because of overdosing (sweating, pallor, nervousness, tremor, tiredness, weakness, confusion, difficulty in concentrating, dizziness, increased appetite, headache, nausea and increased heart beat) - hyperglycemia (high blood sugar) due to underdosing (thirst, increased urination, dehydration, "fruity" odor of the breath or urine, tiredness and difficulties in thinking).

Local reactions at the infusion points are possible (may occur): itching, unusual pain, redness, hives or inflammation. A thickening or thinning of the skin may also occur at the injection site.

Allergic reactions to insulin or solution that contains it are rare; they can be associated with generalized skin reactions and may rarely lead to a life-threatening shock. Rarely, insulin may induce sodium retention and oedema, and very rarely muscle pain. Moreover, despite the beneficial effect of long-term stability of blood glucose on the progression of retinopathy (eye diabetic disease), a significant change in blood sugar can cause a temporary decrease in vision.

Treatment with insulin can lead to the formation in the body of anti-insulin antibodies (substances

that act against insulin).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients already treated with Insuplant 400 IU/mL via Medtronic MiniMed Implantable System 2007
* Signed informed consent form prior to enrolment
Or:
• Being implanted with Minimed Implantable Pump

Exclusion criteria

-

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2011
Enrollment:	68
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	insuman implantable 400IE/ml
Generic name:	insuman implantable 400IE/ml
Product type:	Medicine
Brand name:	insuplant
Generic name:	insuplant

Ethics review

Approved WMO

Date:	22-10-2010

Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	10-01-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-03-2011
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-09-2011
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-12-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-01-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-01-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2010-021373-37-NL
ClinicalTrials.gov	NCT01194882
CCMO	NL34071.075.10