Post Authorisation Safety Study (PASS): an European observational cohort of patients with type 1 diabetes treated via intraperitoneal route with Insuman Implantable 400 IU/mL in Medtronic MiniMed implantable pump (IIMOS)

First published: 04/09/2015

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS10872

Study ID

49593

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France

Study description

This is a multinational, multicenter, observational, prospective cohort study for patients with type I diabetes who are treated with Insuman Implantable 400 IU/mL. The duration of the study is ten years from entry of first patient. The objective of the study is to increase knowledge on the safety profile of Insuman Implantable 400IU/ml delivered by an implantable pump into the intraperitoneal cavity and to monitor the safe use in real life setting. No visits or examinations, laboratory tests or procedures are mandated as part of this study. Visits will occur according to routine clinical practice for use of an implantable pump which is at refill visits (approximately every 40 to 45 days) and at ad hoc visits related to complications of the insulin treatment regimen or pump. Data will be collected by site and entered in an electronic case report form (e-CRF) (on an ongoing basis for adverse events, at three, and six months after study entry and then every six months for other study related information). Discontinuation of the Medtronic MIP led to reduced availability of pumps and implementation of a pump phase out process, which compromised the feasibility of completing the originally planned study. The total projected sample was reduced to 260 patients. It was therefore agreed with the PRAC to terminate the study early, with a maximum observed follow-up of 5.9 years instead of the originally planned 10-years.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sylvia Merk

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/07/2014

Actual: 24/07/2014

Study start date
Planned: 27/04/2016

Actual: 27/04/2016

Data analysis start date
Planned: 19/09/2016

Actual: 19/09/2016

Date of interim report, if expected
Planned: 15/02/2021

Actual: 15/02/2021

Date of final study report
Planned: 30/10/2026

Actual: 21/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi-Aventis

Study protocol

HUBINC06380-final protocol - December 2014.pdf(501.36 KB)

hubin-c-06380-amended-protocol2_20FEB2018.pdf(528.62 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of the study is to better characterize some of the following important identified risks: • Severe hypoglycaemia • Hyperglycaemia

caused by insulin underdelivery due to pump dysfunction or catheter blockage • Pump pocket infection • Abnormal healing (at the surgical incision site after device implantation) • Skin erosion

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multinational, multicenter, observational, prospective study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10AB01) insulin (human)

insulin (human)

Medical condition to be studied

Type 1 diabetes mellitus

Population studied

Short description of the study population

Adult patients with type 1 diabetes who cannot control their diabetes with subcutaneous insulin therapy present with frequent, severe hyper- and/or

hypoglycaemia treated with Insuman Implantable 400 IU/mL.

Inclusion Criteria:

• Patients with type 1 diabetes using Insuman Implantable in a Medtronic MiniMed implantable pump

• Signed written informed consent

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Type 1 diabetes patients

Estimated number of subjects

260

Study design details

Outcomes

• Severe hypoglycaemia • Hyperglycaemia caused by insulin underdelivery due to pump dysfunction or catheter blockage • Pump pocket infection • Abnormal healing (at the surgical incision site after device implantation) • Skin erosion, • hypersensitivity reactions to Insuman Implantable 400 IU/mL, hypersensitivity

reactions to pump material and focal hepatic steatosis, • Safety in pregnant and lactating women and long term safety (including effect of lon

Data analysis plan

Since the primary objective is to monitor the important identified risks, the analysis will be descriptive and the multiplicity control will not be considered. For the important identified risks including severe hypoglycaemia, hyperglycaemia due to underdelivery of insulin, pump pocket infections, skin erosion, and abnormal healing, the time to first event will be depicted by the Kaplan-Meier plot. The cumulative event rate and its 95% confidence interval (CI) will be presented yearly. The cumulative risk over the entire study and the instantaneous risk expressed as the hazard function over time will be presented graphically according to the time expressed in years and using a kernel smoothing method. A horizontal line will represent the incidence rate calculated, as number of patients with one or more events divided by the number of patients treated.

Documents

Study results

hubin-c-06380-final_CSR_abstract.pdf(619.43 KB)

Study publications

Renard E, Guerci B, Jeandidier N. Long-term safety and efficacy of intraperiton...

Renard E, Guerci B, Jeandidier N. Long-term safety and efficacy of intraperiton...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Composition of steering group and observers

HUBINC06380_SC_Members.pdf(12.88 KB)

Data sources

Data sources (types)

Drug registry

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No