

# 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

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### Study ID

49593

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### DARWIN EU® study

No

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### Study countries

 Belgium

 France

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## **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.

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## **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**

[sylvia.merk@iqvia.com](mailto:sylvia.merk@iqvia.com)

### Primary lead investigator

Sylvia Merk

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 24/07/2014

Actual: 24/07/2014

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### Study start date

Planned: 27/04/2016

Actual: 27/04/2016

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### **Data analysis start date**

Planned: 19/09/2016

Actual: 19/09/2016

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### **Date of interim report, if expected**

Planned: 15/02/2021

Actual: 15/02/2021

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### **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

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## 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

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#### Study type:

Non-interventional study

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#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### Data collection methods:

Combined primary data collection and secondary use of data

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#### 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

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### **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)

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### **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
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### **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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Type 1 diabetes patients

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### **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

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### **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)

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### **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...](#)

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## 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)

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## Data sources

### **Data sources (types)**

[Drug registry](#)

[Other](#)

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### **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

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### **Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No