Phoenix:
Clinical evaluation of the Medtronic Implantable Insulin Pump System (MIIPS 2020) in adult subjects with Type 1 Diabetes

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The objective of this study is to evaluate the insulin delivery of the Medtronic Implantable Insulin Pump System (MIIPS 2020).

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

Summary

ID

NL-OMON57171

Source
ToetsingOnline

Brief title
Phoenix

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes type 1, MIIPS (Medtronic implantable insulin pump system

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic Inc.

Intervention

Keyword: Continuous Glucose Monitoring, Diabetic type 1, hyper- and/or hypoglycemia., Implantable Insulin Pump System

Outcome measures

Primary outcome

Primary Endpoint:

Delivery accuracy is critical to MIIPS 2020. For each subject*s pump refill,

the total actual volume dispensed will be compared to the total calculated

volume dispensed to compute the refill accuracy per subject:

Refill Accuracy= (Total Actual Volume Dispensed)

_____

Total Theoretical Volume Dispensed

where the total actual volume dispensed by the pump will be determined by

subtracting the insulin weight removed from the pump at the start of a refill

procedure from the insulin weight placed in the pump during the previous refill

procedure. The theoretical volume dispensed by the pump will be calculated by

the Clinician Controller.

Refill accuracy will be assessed after 4 refill cycles.

Secondary outcome

The safety data associated with diabetes management, specifically in the

subject population indicated to MIIPS, will be summarized:

• Serious Adverse Events (SAE)

• Serious Adverse Device Effects (SADE)

• Unanticipated Serious Adverse Device Effect (USADE)

• Incidence of Severe Hypoglycemia

• Incidence of Severe Hyperglycemia

• Incidence of Diabetic Ketoacidosis (DKA)

The following secondary endpoint will also be calculated to evaluate the

insulin delivery of MIIPS 2020:

• Refill accuracy at each refill visit

• Percentage of pump with accuracy ratio <= 85% prompting NaOH rinse procedures

at each refill visit

Study description

Background summary

Section 4.1 Clinical Protocol

Study objective

The objective of this study is to evaluate the insulin delivery of the
Medtronic Implantable Insulin Pump System (MIIPS 2020).

Study design

The study is a premarket, interventional, prospective, open-label, multi-center study in adult patients with Type 1 diabetes mellitus that cannot be controlled with subcutaneous insulin (including pump) therapy, presenting with frequent, otherwise unexplained severe hyper- and/or hypoglycaemia. No control group has been introduced in the study design because, with the MIIPS 2007 discontinuation, MIIPS 2020 will be the only treatment option for Subjects who need continuous intraperitoneal insulin infusion (CIPII) .
Additional procedures required per study protocol that are considered out of standard of care include the following:
• Pregnancy test
• Blinded CGM
• Questionnaires
• SMBG/Ketone collection (only in the Netherlands)
The study will consist of a run-in period, a study period, and a continued access period.

Run-in Period: During the run-in period, subjects will wear a blinded Medtronic CGM unless they are unable to. The purpose of the run-in period is to collect CGM baseline data while subjects are on their current therapy. The run-in period duration is at least around 3 weeks and may take place up to 12 weeks prior to implant.

Study Period: During the 6-month study period, subjects will be implanted with the MIIPS 2020.

Continued Access Period: Subjects who have completed the study period will be given the opportunity to continue using the investigational study devices until those devices are approved for commercial use and are commercially available.
The total number of patients to be enrolled at each site does not have any specific minimum or maximum requirements, as this study is not statistically powered.
Twenty subjects will complete the study period at up to 12 investigational centers in France and the Netherlands. There is no min/max enrollment requirement for each site. There may be an option to extend enrollment up to 40 subjects based on the data collected from the initial 20 subjects.
Once the first 5 subjects have completed up to Visit 5 (45 ± 7 days), of the study period, an independent Data Monitoring Committee (DMC) will review the subjects* data. Enrollment of subjects may continue after DMC approval.

Intervention

Run-In Period:
Visit 1 (up to 12 weeks before implant) - Office Visit
Screening, informed consent, and blinded CGM initiation

Visit 2 (V1 +21 ± 3 days) - Office Visit
HbA1c collection, confirmation of blinded CGM completion, questionnaire completion, MIIPS 2020 training, schedule of implant

Study Period:
Visit 3 (Day 0) - Office Visit
Implant procedure

Visit 4 (Day 15 ± 3 days) Office Visit
Incision healing evaluation, study device management check

Visit 5 (Day 45 ± 7 days)
Pump refill, assessment of baseline accuracy of pump delivery, provision of supplies for blinded CGM, insulin delivery data download

Visit 6a (V6 - 21 ± 3 days)
Call subjects to start blinded CGM

Visit 6 (Day 90 ± 7 days) - 3 months visit
Confirmation of blinded CGMcompletion, HbA1c collection, pump refill, insulin delivery data download

Visit 7 (Day 135 ± 7 days)
Pump refill, provision of supplies for blinded CGM, insulin delivery data download

Visit 8a (V8 -21 ±3 days)
Call subjects to start blinded CGM

Visit 8 (Day 180 ± 7 days) - 6 months, end of Study Period
Confirmation of blinded CGM completion, HbA1C collection, questionnaire completion, pump refill, insulin delivery data download

Continued Access Period:
Continued Access visits will take place after the last study period visit (Visit 8) and according to the programmed refill schedule (i.e., at 45±7day intervals after Visit 8)

Starting from Visit 9 - Visits 9 to 14
Pump refill, insulin delivery data download, HbA1c collection at Visits 10, 12, and 14

Visit 15
Pump refill, insulin delivery data download, provision of supplies for blinded CGM

Visit 16a (V16 - 21 ± 3 days)

Call subjects to start blinded CGM

Visit 16
Confirmation of blinded CGM completion, insulin delivery data download, HbA1c collection, pump refill

Continued Access Period will continue with pump refills and insulin delivery data download every 45 ± 7 days (visits 17 and above) and HbA1c collection will occur at every other visit from visit 18 onward until market approval of the study device.
Once the study device obtains market approval, a study exit will be completed.

Study burden and risks

The main benefit of this study is that subjects may experience improved glucose control. With any Insulin Pump System, there is a risk that the pump will deliver too much or not enough insulin, resulting in hypoglycemia or hyperglycemia. These risks have been minimized through numerous safety checks and features as well as patient requirements to test glucose levels frequently. Additionally, as with any implantable device, there is a risk of infection at the implant site or erosion of the device through the skin. These risks have been minimized through pre- and post-surgical care and follow-up by investigational center staff.
Additionally, MIIPSs are currently used in a very selected group of patients who cannot achieve stable glucose control despite structured education for subcutaneous insulin pump use leading to swings in glucose concentrations. Clinical trials and literature data showed that those patients may benefit from continuous intraperitoneal insulin infusion in terms of stability of glycaemic control, reduction of hypoglycaemic events and improved quality of life. Therefore, it is expected that these potential benefits to this specific population of subjects outweigh any risk to subjects who choose to participate in the investigation.

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

Subject is aged >= 18 years old.
2. Subject has a clinical diagnosis of Type 1 diabetes for >= 6 months prior to screening as determined via medical record or source documentation by an individual qualified to make a medical diagnosis.
3. Subject with type 1 diabetes mellitus that cannot be controlled with subcutaneous insulin therapy (including external pump), presenting with frequent, otherwise unexplained severe hyper-and/or hypoglycaemia.
4. Subject has access to a reliable support person, defined as an individual who has daily contact with the subject and knows who to contact in the event of an emergency (i.e., caregiver).
5. Subject has the physical and intellectual ability (in the opinion of the study investigator) to operate the MIIP system and to comply with the data reporting requirements of the study.
6. Subject is willing and able to sign and date informed consent, comply with all study procedures as required during the study.

Exclusion criteria

Subject is actively participating in an investigational study (drug or device) wherein he/she has received treatment from an investigational study drug or device before enrollment into this study, that could impact the outcomes of this study; as per investigator and sponsor judgment.
2. Subject has any other disease or condition that may increase risks during

the implant procedure or may preclude the subject from participating in the study, as determined by a physician who is not the principal investigator.
3. Subject has any known or suspected allergy to insulin or implantable materials of the MIIPS (pump and catheter) as determined by a physician.
4. Subject is a woman who is pregnant, of childbearing potential or lactating, or who is neither surgically sterile nor using contraceptives (devices, oral, implanted or other physician-approved contraceptive) or willing to use them, at the time of enrollment.
5. Subject is vulnerable, legally incompetent or illiterate
6. Residence or planned non-pressurized travel at elevations above 10000 feet/3048 meters during the study period (commercial airline travel is acceptable).
7. Planning to engage in activities requiring a descent greater than or equal to 10 feet/3 meters below sea level.
8. Subject has an active infection requiring antibiotic treatment.
9. Subject is a person whose body size is not sufficient to accept implantable pump bulk and weight.
10. Subject has a life expectancy of less than 9 months.
11. Subject has diagnosis of illicit drugs abuse disorder.
12. Subject has diagnosis of marijuana abuse disorder.
13. Subject has diagnosis of prescription drugs abuse disorder.
14. Subject has diagnosis of alcohol abuse disorder.
15. Subject who is unwilling or unable to monitor their glucose level or wear a personal continuous glucose monitor.
16. Subject who is unwilling or unable to make programming modifications to the pump based on glucose level readings.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-11-2024
Enrollment:	5

Type:	Anticipated

Medical products/devices used

Generic name:	Medtronic Implantable Insulin Pump (MIIP) (MMT-2020)
Registration:	No

Ethics review

Approved WMO Date:	11-11-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL84906.000.24