InPenTM User Experience

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The purpose of this study is to evaluate the user experience of InPen* with InPen Diabetes Management App and Guardian * 4 system in adult patients with type 1 diabetes for the design of a future pivotal study.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON51113

Source
ToetsingOnline

Brief title
InPenTM User Experience

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 1 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: CGM (Continuous Glucose measurement), Guardian 4 system, InPen Diabetes Management App, Type 1 diabetes

Outcome measures

Primary outcome

Not applicable

Secondary outcome

Not applicable

Study description

Background summary

in patients with insulin dependent diabetes mellitus, glycemic control is influenced by numerous factors, such as insulin dosage, insulin absorption, timing, physiological/ lifestyle factors such as exercise, food intake, sleep, hormones and illness. These factors may contribute to significant variability in insulin requirements, which makes self-management of diabetes challenging.

For people with diabetes who take insulin, missing an insulin dose may be a frequent occurrence. Until recently, there has been no objective way to know in patients on MDI therapy whether they have actually taken a dose. Therefore, clinicians rely on patient self-reports of insulin administration and must make changes in the insulin regimen with the presumption that the patient is taking their insulin as prescribed. This presumption may lead to over or under treatment, particularly if non-adherence is frequent. Recently, using novel Bluetooth-enabled insulin pen cap technology, non-adherence to insulin in patients with type 1 diabetes and type 2 diabetes was recorded for 24% of bolus insulin administration and 36% of basal insulin administration. [1]
CGM improves a patient*s ability to get rapid and accurate glucose readings, however patients are still required to make hundreds of decisions a day with little guidance on what to eat, what to dose, when to dose [2], and how to manage activities such as exercise.

The InPen* system integrated with real-time CGM (RT-CGM) will provide the patient with intelligent automation, detection, insights, and recommendations that will enable them to make informed diabetes management decisions.

Study objective

The purpose of this study is to evaluate the user experience of InPen* with InPen Diabetes Management App and Guardian * 4 system in adult patients with

type 1 diabetes for the design of a future pivotal study.

Study design

Study Design This study is a multi-center, single arm study in insulin-requiring adult subjects with type 1 diabetes treated with MDI (basal and bolus) therapy.
The total study duration will be approximately 10 weeks long for each participant.
The study consists of a run-in (phase 1) and study phases 2, 3 and 4. See Figure CIP page 12.

Phase 1: Enrollment (Visit 1) and Screening/Start Run-in (baseline/Visit 2) The purpose of the run-in phase is to collect baseline HbA1c and blinded Continuous Glucose Monitoring (CGM) data while subjects are on their current MDI therapy. Blinded CGM using the Guardian* Sensor 3 and Guardian* Link 3 transmitter will be utilized to collect the baseline CGM data for all subjects for two weeks.
Study Phases Phase 2 (Visit 3):
All subjects will utilize a smart bolus insulin pen injector (InPen*) and app with
dose calculator (InPen* Diabetes Management App), and will continue their own SMBG, iscCGM or RT-CGM for two weeks.

Phase 3 (Visit 4):
Subjects will have an on-site or remote follow-up (titration) visit after Phase 2 (4 weeks from start/baseline). Subjects will continue on the InPen and InPen App for another two weeks utilizing the HCP insights gained during the titration follow-up visit. Blinded CGM will be utilized for all subjects.

Phase 4 (Visit 5):
After four weeks of study phase, HbA1c will be collected, all subjects will stop their own SMBG, iscCGM or RT-CGM and will use the devices below (Visit 5):
* InPen* and InPen* Diabetes Management App
* Guardian* 4 system (RT-CGM)
o Guardian* 4 sensor
o Guardian* 4 transmitter
o Guardian* 4 app

After two weeks on the system subjects will connect with the study center for a remote visit (Visit 6).

All subjects will utilize the InPen* system for four weeks and then exit from the study (Visit 7). At the subject exit at Visit 7, HbA1c is collected.

Intervention

Run-In Period: 2 weeks

Visit 1 (Office): Consent only

Visit 2 (Office): Screening/Baseline (including baseline demographics and HbA1c) and Start Run-In
o Eligibility has been confirmed (Visit 1 and 2 may be combined if eligibility criteria are met)
o Collect baseline HbA1c
o Dispense study devices and blinded CGM diary
o Start blinded CGM (Guardian* Sensor 3 and Guardian* Link 3 transmitter)

Study Period: 8 weeks
*
Visit 3 (Office): Phase 2, Day 14 after Visit 2 (window of +4 days)
o End blinded CGM
o Collect blinded CGM Diary
o Dispense study devices
o Start InPen and InPen Diabetes Management App (subject*s will replace their own rapid acting insulin pen for the InPen)
*
Visit 4 (Office/Remote): Phase 3, Day 14 after Visit 3 (window of +4 days)
o Dispense study devices and blinded CGM Diary
o Review Insight Report
o Start blinded CGM (Guardian* Sensor 3 and Guardian* Link 3 transmitter) with subjects continuing their own SMBG, iscCGM or RT-CGM system
*
Visit 5 (Office): Phase 4, Day 14 after Visit 4 (window of +4 days)
o End blinded CGM
o Collect blinded CGM Diary
o Collect HbA1c
o Continue InPen* with InPen Diabetes Management App and start Guardian* 4 system (subject*s will stop their own SMBG, iscCGM or RT-CGM)

Visit 6 (Remote): Phase 4, Day 14 after Visit 5 (window of +4 days)
o Review Insights Report
*
Visit 7 (Office): End of Study, Day 28 after Visit 5 (window of +4 days)
o Collect HbA1c
o Return study devices

Study burden and risks

The data collected has the potential to facilitate the development and availability of improved Medtronic devices that may provide significant benefits to patients in the future. In light of this, we believe that the overall future potential benefits to the general population of patients with diabetes 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

1.Subject is aged 18-75 years at time of screening
2.Subject is on MDI therapy (defined as * 3 insulin injections per day and on a basal/bolus regimen) *1 year prior to screening
3.Subject has a clinical diagnosis of type 1 diabetes for 1 year prior to

screening
4.Subject has a Glycosylated hemoglobin (HbA1c) less than 10% as assessed by local lab <15 days prior to screening or at time of screening visit
5.Subject is on MDI therapy with
a. SMBG,
b. Continuous Glucose Monitoring (CGM), or
c. Intermittent Scanning CGM (iscCGM)
6.Subject is willing to upload data from a BG meter, must have internet access and a compatible computer system that meets the requirements for uploading data at home.
7.Subject is willing and able to sign and date informed consent, comply with all study procedures, and wear all study devices, as required during the study.
8.Subject is willing to take or switch to one of the following insulins:
a. Humalog** (insulin lispro injection)
b. NovoLog** (insulin aspart)

Exclusion criteria

1. Women of child-bearing potential who have a positive pregnancy test at screening or plan to become pregnant during the course of the study.
2. Women who are breastfeeding.
3. Subject has any unresolved adverse skin conditions in the area of sensor placement (e.g. psoriasis, dermatitis herpetiformis, rash, Staphylococcus infection).
4. Subject is actively participating in an investigational study (drug or device) wherein he/she has received treatment from an investigational study drug or device in the last 2 weeks before enrollment into this study, as per investigator judgment.
5. Subject is currently abusing illicit drugs, marijuana, alcohol or prescription drugs (other than nicotine), per investigator judgment.
6. Subject has any other disease or condition that may preclude the patient from participating in the study, per investigator judgment.
7. Subject is legally incompetent, illiterate or vulnerable person.
8. Research staff involved with executing the study.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	nPen &InPen Diabetes Management App
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-11-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL77928.078.21