ISRCTN78298012 https://doi.org/10.1186/ISRCTN78298012

Looking at the effect of the smart multiple daily injections (MDI) system (inPen™) in type 2 diabetes

Submission date
28/11/2024

Recruitment status
No longer recruiting

Registration date
20/03/2025

Overall study status
Completed

Last Edited
19/03/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to determine if using the InPen™ Smart MDI system is more effective for treating Type 2 diabetes compared to standard insulin pens with continuous glucose monitoring (CGM) sensors. The InPen™ system includes a smart insulin pen and Simplera™ CGM sensors, which together help track insulin doses, remind users to take insulin, and advise on insulin doses through a mobile app. Up to 78 adults in the UK will participate in this study.

Who can participate?
Adults aged 18 years or older with Type 2 diabetes who have been using insulin for more than 2 years, are on a basal bolus regimen with at least 2 bolus doses a day, have an HbA1c level of 8.0% or higher, and are using stable doses of GLP-1 and/or SGLT2i. Participants must be willing to use the study CGM, connect data via the cloud, and use specific brands of quick-acting insulin.

What does the study involve?
Participants will be randomly assigned to one of two groups: one using the standard general anesthesia and the other using regional anesthesia. Both groups will complete a pain questionnaire before surgery and at 6 and 24 hours after surgery. The study will also record the use of painkillers and opioids, any complications within 24 hours after surgery, and the length of hospital stay.

What are the possible benefits and risks of participating?
Participants who receive regional anesthesia may experience lower pain levels after surgery. There are no additional risks compared to the usual procedure.

Where is the study run from?
University of Leicester (UK)

When is the study starting and how long is it expected to run for?
November 2024 to June 2026

Who is funding the study?
Medtronic (UK)

Who is the main contact?
Prof. Pratik Choudhary, pratik.choudhary@leicester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Pratik Choudhary

ORCID ID
https://orcid.org/0000-0001-7635-4735

Contact details
Leicester Diabetes Centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW
+44 116 258 4384
pratik.choudhary@leicester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
346494

Central Portfolio Management System (CPMS)
64508

Protocol serial number
1030

Study information

Scientific Title
Assessing the impact of inPen™ Smart MDI System in type 2 diabetes

Acronym
ASSIIST

Study objectives
To evaluate the efficacy of the InPen Smart MDI device on glycaemic control versus usual care in patients with Type 2 diabetes at 12 weeks.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Study design
To evaluate the efficacy of the InPen Smart MDI device on glycaemic control versus usual care in patients with Type 2 diabetes at 12 weeks.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Randomised study with two arms. Randomisation using online tool.

Arm 1: On-going standard care with InPenTM Insulin pen with SimpleraTM CGM (without using Smart Bolus advisor)
Arm 2: The InPenTM Smart MDI System intervention with SimpleraTM CGM (Using Smart Bolus advisor)

Participant will be on either arm for 24 weeks with an interim analysis at 12 weeks. There will be no follow up.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SimpleraTM CGM + connected InPenTM smart insulin pen (using the smart features on the InPenTM App)

Primary outcome(s)
1. Change in HbA1c is measured using blood tests at baseline, 12 weeks, and 24 weeks
2. HbA1c levels are measured using blood tests at 12 weeks and 24 weeks
3. Adjusted mean difference in HbA1c between groups is measured using linear regression analysis at 12 weeks and 24 weeks
4. Confidence intervals for HbA1c levels are measured using statistical analysis at 12 weeks and 24 weeks

Key secondary outcome(s)
1. Difference in % Time spent in range with sensor glucose (SG) between 70-180 mg/dL (3.9-10.0 mmol/L) over 12 weeks of the study phase. Interpretation of CGM data at 12 weeks

2. Difference in % Time spent in hyperglycaemic range with SG > 180 mg/dL (> 10.0 mmol/L) over 12 weeks of the study phase. Interpretation of CGM data at 12 weeks
3. Difference in % Time spent in hypoglycaemic range with SG < 70mg/dL (< 4.0mmol/l) and <54mg/dL (< 3mmol/l) over 12 weeks of the study phase. Interpretation of CGM data at 12 weeks
4. Number of biochemical hypoglycaemic events< 54 mg/dL (3.0 mmol/L), defined as sensor values < 54 mg/dL (3.0 mmol/L) per 15 consecutive minutes. Interpretation of CGM data at 12 weeks
5. Change between run-in phase and study phase in TIR (3.9-10.0 mmol/l) and TBR (< 3.9 mmol/l) in the control group vs the intervention group. Interpretation of CGM data at 12 week
6. Difference in glucose variability (CoV and SD). Interpretation of CGM data at 12 week
7. Change in total daily dose of insulin from baseline to end of study. Review of insulin dose and CGM data at 12 and 28 weeks
8. Change in other diabetes related medication usage from baseline to end of study. Review of medication at 12 weeks
9. Change in scores from the Type 2 diabetes distress assessment system (T2-DDAS), the DAWN2 Impact of Diabetes Profile (DIDP), System Usability Scale (SUS) and EQ 5d 5L questionnaire. By using respective questionnaires at 0, 12 and 24 weeks
10. Change in Hypoglycaemia Confidence Scale, Clarke and Gold scores. By using respective questionnaires at 0, 12 and 24 weeks
11. Change in Time in ranges from week 12 to week 24 in the control arm. Interpretation of CGM data at 12 and 24 weeks
12. Difference in missed boluses and number of boluses per day. Interpretation of CGM data at 12 and 24 weeks

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. The subject is age ≥18 years old at time of screening
2. Clinical diagnosis of type 2 diabetes [use of insulin >2 years after diagnosis]
3. > 90 days on a basal bolus regimen with >2 bolus doses a day
4. Subject has a glycosylated haemoglobin (HbA1c) ≥8.0% (64 mmol/mol) at time of screening visit (in last 3 months)
5. Using stable doses of GLP-1 and/or SGLT2i (For past 3 months)
6. The subject is willing to use the study CGM and connect data via the cloud
7. Subject is willing and able to sign and date informed consent, comply with all study procedures, and use study devices, as required during the study
8. Subject is on Humalog , Novolog, Novorapid, Lyumjev or Fiasp
9. Subject is willing to use Humalog/Novolog/Novorapid/Fiasp/Lyumjev if using any other brand of quick acting insulin

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subject has had CKD stage 4 or more defined by creatinine clearance <30 ml/min, as assessed by local lab test ≤ 6 months before screening or performed at screening at local lab, as defined by the creatininebased Cockcroft or MDRD equations or receiving dialysis.
2. Subject has a history of hearing or vision impairment hindering perception of glucose display and alarms, or otherwise incapable of using the study devices, per investigator judgment.
3. Subject has any unresolved adverse skin conditions in the area of sensor placement (e.g., psoriasis, dermatitis herpetiformis, rash, Staphylococcus infection).
4. The 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.
5. The subject is legally incompetent, illiterate, or vulnerable person.
6. Any diagnosis of diabetes other than type 2 diabetes including those secondary to chronic disease.
7. In the investigator's opinion, intensification of glucose therapy is not suitable for the participant, such as other comorbidities or frailty.
8. Participant is currently on a mixed therapy combination with basal insulin (i.e., basal insulin with any other glucose-lowering therapy administered as a combined medication), e.g., Xultophy.
9. In the investigator's opinion the participant has any other concomitant disease or condition that may compromise patient safety and/or interfere with the normal conduct of the study and /or interpretation of the study results, including and not limited to; unstable coronary heart disease, learning disabilities, severe mental illness (such as psychotic disorder, bipolar disorder, dementia, substance and/or alcohol dependence, depression with active suicidal ideation), a known or suspected eating disorder, or any other uncontrolled medical condition.
10. Currently prescribed or anticipated short term use of glucocorticoid therapy (oral, intra-articular, intramuscular, or intravenous) for any acute condition.
11. Known (or suspected) allergy to medical grade adhesives at enrolment.
12. Currently participating in another study that could affect glucose measurements or glucose management.
13. Has a planned major medical intervention expected to significantly alter red cell lifespan such as, chemotherapy, major surgery requiring blood transfusion or has a history of blood transfusion in the last three months.
14. A female participant who is pregnant, planning to become pregnant within the next 6months or becomes pregnant/ breastfeeding during the study.

Date of first enrolment
06/01/2025

Date of final enrolment
06/07/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Leicester Diabetes Centre
Leicester General Hospital NHS Trus
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request submitted in writing to the study Chief Investigator: Professor Pratik Choudhary: Pratik.Choudhary@leicester.ac.uk

IPD sharing plan summary
Available on request