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An observational study of adults living with type 1 diabetes

Submission date
10/03/2021

Recruitment status
No longer recruiting

Registration date
15/03/2021

Overall study status
Completed

Last Edited
22/04/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 1 diabetes causes the level of glucose (sugar) in your blood to become too high. It happens when your body cannot produce enough of a hormone called insulin, which controls blood glucose.
The advent of automated insulin delivery (AID) systems provides the potential to significantly improve diabetes management among people with Type 1 Diabetes.
The aim of this study is to assess whether do-it-yourself AID systems are equivalent to commercial AID systems in terms of effectiveness for glycemic control, safety and quality of life among adults living with type 1 diabetes in real-life conditions.

Who can participate?
To participate in this study, patients must have been living with Type 1 Diabetes for more than one year, be 18 years old and over, and have been using AID therapy for more than 3 months.

What does the study involve?
The study involves 5 visits that can be undertaken over approximately 12 weeks. Participants will wear an additional glucose sensor for 4 weeks and answer questionnaires to assess quality of life. At the end of those four weeks, we will ask them to return the additional glucose sensors to the research team.

What are the possible benefits and risks of participating?
Participants may obtain a personal benefit from participating in this research project, but we cannot guarantee it. The only direct benefit is the possibility to receive a refreshment education on how to manage acute hypo and hyperglycemic conditions. In addition, we hope that the results of this study will allow us to assess the comparative effectiveness and safety of various AID systems in type 1 diabetes.
Possible risks of participating include a risk of infection, irritation and/or slight discomfort at the points of insertion for the Dexcom G6 sensors; certain side effects associated with participants' medical condition and their AID therapy; hypoglycemia; and hyperglycemia.

Where is the study run from?
The study is being run from the Montreal Clinical Research Institute in Montreal, Québec, Canada.

When is the study starting and how long is it expected to run for?
December 2020 to March 2023

Who is funding the study?
The study is funded by the Canadian Institutes of Health Research

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2021-1110

Study information

Scientific Title

Comparison between two types of novel insulin delivery systems among adults living with type 1 diabetes

Acronym
MILESTONE

Study objectives
Do-it-yourself automated insulin delivery therapy is non-inferior to commercial automated insulin delivery therapy in terms of effectiveness for glycemic control, safety and quality of life among adults living with type 1 diabetes in real-life conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/03/2021, Research Ethics Board of the Montreal Clinical Research Institute (110 Avenue des Pins West, Montréal, Québec, H2W 1R7, Canada; +1 (514) 987-5550; Brigitte.St-Pierre@ircm.qc.ca), ref: 2021-1110

Study design
Prospective single-center non-inferiority non-randomized parallel-cohort observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
This is an observational study. Participation in this research project will last approximately 12 weeks and will include 5 visits. Participants will wear an additional glucose sensor for 4 weeks and answer questionnaires to assess quality of life.

Intervention Type
Other

Primary outcome(s)
Percentage of time of glucose levels spent between 3.9 and 10.0 mmol/L (TIR%) measured using a worn glucose sensor over 4 weeks

Key secondary outcome(s))
Measured using a worn glucose sensor over 4 weeks:
1. Percentage of time of glucose levels. between 3.9 and 7.8 mmol/L; b. below 3.9 mmol/L; c. below 3.0 mmol/L; d. above 10.0 mmol/L; e. above 13.9 mmol/L
2. Mean glucose levels
3. Estimated HbA1c
4. Standard deviation (SD) and coefficient of variance (CV) of glucose levels
5. Episodes of hypoglycemia/hyperglycemia

6. Glucose area under the curve
7. Risk of hypoglycemia and hyperglycemia (low blood glucose index [LBGI] and high blood glucose index [HBGI]) measured using data from the glucose sensor over 4 weeks
8. Scores for QoL questionnaires (Hypoglycemia Fear Survey II, Diabetes Distress Scale, Diabetes Treatment Satisfaction Questionnaire, Pittsburgh Sleep Quality Index, and Audit of Diabetes Dependent Quality of Life) at baseline
9. SD and CV of insulin delivery measured using insulin records of 7 representative previous days of insulin therapy at week 4
10. Total insulin delivery measured using insulin records of 7 representative previous days of insulin therapy at week 4
11. Total number of hours and percentage of time of sensor availability

Completion date
15/01/2023

Eligibility

Key inclusion criteria
1. Males and females ≥18 years old
2. Clinical diagnosis of type 1 diabetes for at least 1 year (The diagnosis of type 1 diabetes is based on the investigator's judgment; C-peptide level and antibody determinations are not needed)
3. Having been on AID therapy for at least 3 months
4. Willing to carry an additional CGM and a receiver for 30 days to collect blinded CGM data
5. Accepting that their pump setting parameters to be collected by the research team. This access will be limited to the study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
78

Key exclusion criteria
1. Using regular insulin (Entuzity U500, Novolin ge Toronto or Humulin R)
2. Clinically significant nephropathy (eGFR <15 ml/min/1.73m², planned or on dialysis), neuropathy (e.g., known uncontrolled gastroparesis) or retinopathy (e.g., proliferative retinopathy with ongoing active treatment such as laser photocoagulation or planned surgery)

as judged by the investigator
3. Recent (<6 months) acute macrovascular event (e.g., acute coronary syndrome or cardiac surgery)
4. Anticipated therapeutic change (including change of insulin, CGM sensor or AID system type) between admission and end of the study
5. Anticipated need to use acetaminophen during the study period
6. Pregnancy (ongoing or current attempt to become pregnant)
7. Breastfeeding
8. Plan to go abroad in a foreign country during the study period
9. Severe hypoglycemic episode within two weeks of screening
10. Severe hyperglycemic episode requiring hospitalization in the last 3 months
11. Current use of glucocorticoid medication (except low stable dose and inhaled steroids and stable adrenal insufficiency treatment e.g., Cortef®)
12. Agents affecting gastric emptying (Motilium®, Victoza®, Ozempic®, Trulicity®, Byetta® and Symlin®) as well as oral anti-diabetic agents (Metformin, Prandase®, DPP-4 inhibitors) unless at a stable dose for 3 months and without anticipated change during the study.
13. Current use of SGLT-2 inhibitors unless at a stable dose for at least 3 months, without anticipated change during the study and appropriate ketone testing is performed
14. Known or suspected allergy to the study products (e.g., Dexcom adhesive)
15. Other serious medical illness likely to interfere with study participation or with the ability to complete the study by the judgment of the investigator
16. Anticipation of a significant change in exercise or diet regimen between admission and end of the study (i.e., starting or stopping an organized sport; planned significant diet change)
17. Anticipated radiologic examination at the time of study assessment incompatible with CGM wear (e.g., MRI)
18. In the opinion of the investigator, a participant who is unable or unwilling to observe the contraindications of the study device

Date of first enrolment
31/03/2021

Date of final enrolment
10/01/2023

Locations

Countries of recruitment
Canada

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Sponsor information

Organisation
Montreal Clinical Research Institute (IRCM)

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the Montreal Clinical Research Institute. With the participant's written consent, the data collected during this study will also be added to the PROMD biobank. All the datasets generated during and/or analysed during this study will remain confidential to the extent provided by law. Participants will only be identified by a code number. The key to the code linking participants to their data will be kept by the researcher responsible for this study. The researcher responsible for this study could forward your coded data to the DIYAID community for the purpose of improving algorithms. The researcher responsible for this study could also forward your coded data to healthcare authorities (e.g., Health Canada) for the purpose of assessing the benefits and limitations of different AID systems. However, the researcher responsible and any entities who receive the research data will respect the confidentiality rules in effect in Quebec and Canada regardless of the country to which your data may be transferred. The study data will be stored for at least 25 years by the researcher responsible for this study.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/03/2025	22/04/2025	Yes	No