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Assessment of glucose levels and insulin requirements during the menstrual cycle in women with type 1 diabetes using an automatic insulin delivery system

Submission date
07/11/2024

Recruitment status
Recruiting

Registration date
18/11/2024

Overall study status
Ongoing

Last Edited
11/03/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Women living with type 1 diabetes (T1D) face various reproductive challenges throughout their lives. One of these challenges is the effect of the menstrual cycle on glucose control. Despite advances in T1D management, hyperglycemia (high blood sugar) in the luteal phase remains a common issue.
Most women with T1D need to adjust their insulin doses according to their menstrual cycle variations, which may lead to suboptimal outcomes. Hyperglycemia is often observed during the premenstrual or menstrual period, and hypoglycemia (low blood sugar) may occur in the follicular phase if high doses are continued. A potential solution to this problem is a closed-loop insulin delivery system that can adapt to the changing insulin needs associated with the menstrual cycle.
Food cravings have been described as part of the premenstrual syndrome in non-diabetic women. However, there is very scarce information on whether women living with T1D exhibit increased food intake before the menstrual period and how this might affect glucose control. Traditionally, fluctuations in insulin requirements associated with the menstrual cycle have been addressed by adjusting insulin administration, especially basal insulin, during the days preceding the bleeding. However, few patients can adjust carbohydrate/insulin or sensitivity ratios to compensate for the need for more insulin. This study aims to evaluate the number of daily meals and daily carbohydrate ingestion during the menstrual period and the amount of insulin used as an autobolus. We hypothesize that some women will report increased food intake, and more autobolus will be administered during the luteal phase compared to the follicular phase. This study aims to compare automation's impact on women's glycemic management during menstrual cycles. Additionally, the effect of other factors, such as food intake and insulin requirements, will be assessed at different phases of the cycle.

Who can participate?
Adolescents and young adult women living with type 1 diabetes treated with an automated insulin delivery system (Medtronic 780g). Adolescents will be recruited only if they had their menarche at least 2 years ago. Adult women must be younger than 35 years.

What does the study involve?
The adolescents and young women living with type 1 diabetes and using the Medtronic 780g will need to report the first date of the menstrual cycle and answer a questionnaire about cravings. A follow-up of the menstrual cycles will be done at least for 3 months and 8 months at most. Data on daily insulin administration and food intake in the different phases of the menstrual cycle will be downloaded from the Carelink online database.

What are the possible benefits and risks of participating?
The only benefit of participating in this study will be that new knowledge will arise to understand if AID systems are a genuine help for helping glucose level fluctuations in women with T1.

Where is the study run from?
Institute of Maternal and Child Research, Hospital San Borja Arriarán, Santiago, Chile

When is the study starting, and how long is it expected to run for?
February 2024 to January 2026

Who is funding the study?
Medtronic (USA)

Who is the main contact?
1. Dr Franco Giraudo, francogiraudo@uchile.cl
2. Prof. Ethel Codner, ecodner@uchile.cl

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Assessment of glucose levels and insulin requirements during the menstrual cycle in women using Medtronic 780G

Acronym
AID and Menstrual Cycle in T1D

Study objectives
Women with type 1 diabetes who use automated insulin delivery show similar glucose levels in the premenstrual period compared to the follicular period.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/12/2023, Comité Ético Científico del Servicio Metropolitano de Salud Central (Ethical Scientific Committee of the Central Metropolitan Health Service) (Victoria Subercaseaux 381, Santiago, 8320143, Chile; +56 (0)2-25746900; comite.eticossmc@redsalud.gob.cl), ref: acta 71-19 N°375/2023

Study design
Prospective longitudinal follow-up

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Young adult and adolescent women with type 1 diabetes

Interventions
Follow-up of women using an automated insulin delivery system (Medtronic 780G) that can deliver insulin as needed. T he researchers will assess glucose levels and insulin delivery in the luteal and follicular phases by downloading the data from Carelink, an online database that saves glucose levels and insulin administered by the insulin infusion device (Medtronic 780G).

Women who fulfil inclusion/exclusion criteria and are willing to register their menstrual cycles will be invited to participate.

An assessment of BMI, age, metabolic control, medications, and contraception will be tabulated.

A longitudinal follow-up will be carried out for at least 3 months. Phone calls or messages will be sent to ask for the day of the last menstrual period. An optional invitation will be extended to continue the follow-up for three additional months.

A questionnaire will be administered to evaluate the intensity of cravings during the premenstrual and follicular phase.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Automated insulin delivery system (Medtronic 780G)

Primary outcome measure
Continuous glucose monitoring will determine the ambulatory glucose profile (Guardian 3 or Guardian 4, Medtronic, Inc.), which measures interstitial glucose levels every five minutes. This data is downloaded to an online database (Carelink). The ambulatory glucose profile will be determined in the early follicular and late luteal phases for at least three menstrual cycles—the definition of the early follicular and late luteal phase. •The initiation of the bleeding will be considered day 1. Early follicular phase: days 1 to 4 of the cycle or 2-4 if initiation of bleeding is not precise.
Late luteal phase: days -3 to -1 of the cycle
The following variables will be obtained from the continuous glucose monitoring system and determined for the different menstrual cycles:
1. Time in range (proportion of time that the patient has interstitial glucose in the 70-180 mg/dl range)
2. Mean glucose levels: mean glucose level of the period.
3. Coefficient of glucose variability,
4. Time below range (<70 mg/dl)

Secondary outcome measures
The amount of extra insulin that the insulin infusion pump algorithm gives to achieve normal glucose levels will be determined in the follicular and luteal phases. This will be defined as the number of daily units of insulin and the proportion of the total basal insulin administration.

Overall study start date
01/06/2023

Completion date
30/01/2026

Eligibility

Key inclusion criteria
1. Diagnosis of T1D is clear. Diagnosis of T1D will be based on the need for insulin treatment from the onset of the disease and clinical diagnosis of T1D. The characteristics of the menstrual cycle will not be an inclusion or exclusion criterion
2. Younger than 35 years of age.
3. Users of 780G
4. At least 2 years post-menarche
5. Willing to track menstrual cycles with an electronic app

Participant type(s)
Patient

Age group
Adult

Lower age limit
12 Years

Upper age limit
35 Years

Sex
Female

Target number of participants
20

Key exclusion criteria
1. Amenorrhea (>90 days) during the last semester
2. Use of hormonal contraception
3. Subjects whose diagnosis of the type of diabetes is unclear will be excluded
4. The presence of the honeymoon period (<0.5 IU/kg/day of insulin)
5. T1D of one year or less of duration will lead to the exclusion of the subject
6. Chronic use of steroids or anticonvulsants
7. Pregnancy or delivery in the last 6 months
8. Breastfeeding
9. Severe concomitant illness
10. Uncontrolled hypothyroidism (last TSH >10 IU/ml in the past year)
11. Hypogonadism, or other hormonal deficiencies

Date of first enrolment
02/01/2024

Date of final enrolment
30/12/2025

Locations

Countries of recruitment
Chile

Study participating centre
University of Chile
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Sponsor information

Organisation
University of Chile

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University/education

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ROR
https://ror.org/047gc3g35

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/10/2026

Individual participant data (IPD) sharing plan

The data downloaded from the patients is stored in the Carelink database.
The datasets generated and analysed during the current study will be available upon request to Prof. Ethel Codner (ecodner@uchile.cl) or Dr Franco Giraudo (francogiraudo@uchile.cl.cl)

IPD sharing plan summary

Available on request