ISRCTN29256651 https://doi.org/10.1186/ISRCTN29256651

Contraception in type 1 diabetes

Submission date
21/06/2017

Recruitment status
No longer recruiting

Registration date
27/06/2017

Overall study status
Completed

Last Edited
22/07/2025

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 (T1D) is one of the most common chronic diseases of childhood, causing blood sugar levels to become too high. When children with T1D become teenagers or young adults, managing their diabetes is very important due to risky behaviours like unplanned pregnancies. Most young adults are not aware that there can be complications with both the mother and baby due to diabetes, such as birth malformations. Conception should be planned when the mother has normal blood sugar levels. It is important to provide education, counselling and contraception (methods to prevent pregnancy) in young women both with and without T1D. Contraception usually involves hormones (chemical messengers that control the bodies functions), such as birth control or an implantable medical device. Research is needed to examine what the metabolic effects (how food is processed to energy) of hormonal contraception in teenagers with T1D. Previous research has shown that hyperandrogenism (too much male sex hormones) and inflammation (swelling) are frequent problems in women with T1D. Another consideration in this study is to examine the impact of T1D and the use of contraceptives on telomere length. Telomere is the ending portion of the chromosome (part of the genes that carry out genetic information). Telomere length decreases with advancing age and is shortened in cases of type 2 diabetes. Recently, it was shown that the use of COC in adolescents with polycystic ovary syndrome (a syndrome that affects how a womens ovaries work causing irregular periods and other symptoms) decreases telomere length. Whether telomere length is affected by T1D in young women or by the use of contraceptives in these young women, is unknown. The aim of this study is to examine the impact of different types of contraception on young women with T1D when compared to young women without T1D.

Who can participate?
Young women aged 16 to 25 who have T1D and healthy women aged 16-25 years old.

What does the study involve?
Participants are provided counselling about contraception and pregnancy prevention. They are then offer either a contraceptive pill (taken by mouth) or the implantable rods as birth control methods. Participants are followed up for two years and provide blood samples before taking the contraception and at three, six, 12 and 24 months. The women with T1D and the women without are compared to see how the contraception impacts their metabolic control, bone mass, insulin sensitivity and telomere length.

What are the possible benefits and risks of participating?
Participants may benefit from receiving the contraceptive methods and medical control without cost for them. The only risk of the study is the already reported as well-known possible side effects of hormonal contraception.

Where is the study run from?
1. University of Chile (Chile)
2. Instituto Chilena de Medicina Reproductiva (ICMER) (Chile)

When is the study starting and how long is it expected to run for?
May 2017 to April 2021

Who is funding the study?
Fondecyt (Chile)

Who is the main contact?
Professor Ethel Codner

Contact information

Type(s)
Scientific

Contact name
Prof Ethel Codner

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FONDECYT 1170895

Study information

Scientific Title

Metabolic effect of the long-acting reversible contraceptive method (implant) compared to combined oral contraceptive in young women with type 1 diabetes

Study objectives
Adolescents/young women with T1D receiving hormonal combined oral contraception or a long-acting reversible method (implantable progesterone rod) exhibit a detrimental profile of markers associated with inflammation, insulin resistance, and telomere length compared with healthy non-diabetic young women receiving the same type of contraception. As wel, T1D young women will show lower bone mass than healthy young women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB of the Servicio Salud Metropolitano Central (SSMC) of the Health Ministry of Chile, 29/05/2017, ref: N°431/2017

Study design
Interventional non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Young women with type 1 diabetes or healthy controls.

Interventions
Healthy participants and participants with T1D (N:40) seeking contraception are recruited. Counseling about contraception and pregnancy prevention is given to both groups of women.

Participants are offered either a combined oral contraceptive pill containing ethinyl estradiol 30 ug/desogestrel 0.15mg, or the implantable rod with etonogestrel, the active metabolite of desogestrel. Both methods are currently available for women of this age group and have been considered as first-line options for young women.

Participants are followed for two years and blood samples are obtained at baseline, three, six, 12, and 24 months.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Implanon (R) contraceptive implant and desogestrel/ethynil estradiol

Primary outcome measure
1. Inflammatory markers is measured using C-Reactive Protein Levels at baseline, three, six, and 12 months
2. Metabolic control (HbA1c) is measured using HbA1c with DCA-2000 (Siemens) equipment at month three, six, nine and 12
3. Bone Mass is measured using DXA (Lunar Prodigy GE) at baseline, 12 and 24 months
4. Insulin sensitivity is measured using estimated insulin sensitivity index, which includes the measurement of adiponectin and was validated for subjects with and without T1D6 at baseline, three, six, and 12 months
5. Telomere length is measured using blood tests at baseline and at 12 months

Secondary outcome measures
1. Metabolic control will be assessed at 18 and 24 months in women with type 1 diabetes
2. Bone mass DXA (Lunar Prodigy GE) and insulin sensitivity in all the participants is assessed using DXA (Lunar Prodigy GE) and insulin sensitivity index at 24 months of treatment

Overall study start date
02/05/2017

Completion date
30/04/2021

Eligibility

Key inclusion criteria
T1DM patients:
1. Clinical diagnosis of T1D is clear (patient received treatment with insulin from the time of diagnosis with clinical evidence of severe insulin deficiency).
2. Age: 16-25 years old.
3. Seeking contraception.
4. HbA1c lower than 13%
5. Has not used hormonal contraception for the last three months

Healthy subjects:
1. Age 16-25 years old
2. Seeking contraception
3. Has not used hormonal contraception for the last three months

Participant type(s)
Mixed

Age group

Mixed

Lower age limit
16 Years

Upper age limit
25 Years

Sex
Female

Target number of participants
Based in this meta-analysis of effects of combined oral contraception on PCR levels, the required number of subjects needed to observe differences in is ten young women in each arm of the study. However, the continuation of the implant and combined oral contraception in adolescents after 24 months of use is 77% and 45%, respectively. Therefore, an initial sample size of twenty subjects in each arm is calculated to be sufficient to find differences in C-peptide levels throughout the study.

Total final enrolment
80

Key exclusion criteria
Both groups of subjects (patients with type 1 diabetes and healthy controls):
1. Chronic conditions such as celiac sprue, epilepsy, cardiopulmonary or gastrointestinal conditions are present.
2. Use of steroidal medication.
3. Contraindications for using hormonal contraception (WHO criteria: migraine with aura, prothrombotic problems, etc)

Persons with type 1 diabetes:
1. HbA1c higher than 12.9%
2. Honeymoon period
3. Other type of diabetes

Healthy controls:
1. Menstrual cycle abnormalities according to the American Academy of Pediatrics.

Date of first enrolment
01/07/2017

Date of final enrolment
30/03/2020

Locations

Countries of recruitment
Chile

Study participating centre
University of Chile
Institute of Maternal and Child Research (IDIMI)
Santa Roa 1234
Santiago
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Study participating centre
Instituto Chilena de Medicina Reproductiva (ICMER)
José Victorino Lastarria 29 dp 101
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Sponsor information

Organisation
University of Chile

Sponsor details
Facility of Medicine (Facultad de Medicina)
Av. Independencia 1027
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Sponsor type
University/education

Website
http://www.uchile.cl/investigacion

ROR
https://ror.org/04teye511

Funder(s)

Funder type
Research council

Funder Name

Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Publication and dissemination plan
planned presentation in meetings related to Diabetes and Endocrinology during 2020 and 2021. In addition, publication in a high-impact peer reviewed journal at the end of the study.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ethel Codner at ecodner@med.uchile.cl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/11/2023	30/01/2024	Yes	No
Results article		07/05/2024	22/07/2025	Yes	No