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Metformin for the treatment of hyperandrogenism in adolescents with type 1 diabetes mellitus

Submission date
28/01/2013

Recruitment status
No longer recruiting

Registration date
06/02/2013

Overall study status
Completed

Last Edited
06/02/2013

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
There is an increased prevalence of hyperandrogenism (excessive production of male hormones) in women with type 1 diabetes. We do not know the best treatment for this condition. This study evaluated the effect of an insulin-sensitizing drug called metformin which has been used for the treatment of hyperandrogenism in women without type 1 diabetes. We investigated the effect of metformin on hyperandrogenism and ovulation in adolescents with type 1 diabetes mellitus.

Who can participate?
Women younger than 22 years who have type 1 diabetes and either increased body hair (hirsutism) or elevated androgen plasmatic levels participated.

What does the study involve?
Participants were randomly allocated to take either metformin (850 mg twice a day) or a pill without any medication (placebo twice a day) for nine months. A hormonal study was performed at the beginning and at the end of the study and an assessment of menstrual cycles and presence of ovulation was carried-out throughout the study. No healthy volunteers were included in this study.

What are the possible benefits and risks of participating?
The benefits of participating included a monthly evaluation by a nurse and diabetologist.
Side effects were mainly nausea or abdominal discomfort, at the beginning of the treatment. Metformin has been studied in many adults and adolescents with type 1 diabetes and no major side effects have been reported.

Where is the study run from?
The lead centre taking part in this trial is Instituto de Investigaciones Materno Infantil, School of Medicine, University of Chile. This is an academic centre located in a General Hospital (Hospital San Borja Arriarán) in Santiago, Chile. Some patients were referred from Hospital Calvo Mackena in Santiago, Hospital de Talca and Concepción (Chile).

When is the study starting and how long is it expected to run for?
January 2005 to January 2008.

Who is funding the study?
The study was funded by a Chilean governmental organism, Fondecyt. The support was started in 2005 and finished in 2008.

Who is the main contact?
Dr. Ethel Codner
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Fondecyt Grant 1050452

Study information

Scientific Title
Metformin for the treatment of hyperandrogenism in adolescents with type 1 diabetes mellitus: a double blind randomized study

Study objectives
It is hypothesized that metformin will be a useful treatment for adolescents with type 1 diabetes and hyperandrogenism.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Chilean Ministry of Health, Central Metropolitan Service, Resolution 24/07, 27 August 2004

Study design
9 months double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Metformin 850 mg twice a day or placebo given twice daily.

Total duration of intervention: 9 months

Hormonal measurement in a blood sample at the beginning and end of the protocol

Menstrual cycle duration and ovulation assessment

In order to asses ovulation, measurement of progesterone in blood obtained together with capillary blood glucose measurement.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Metformin

Primary outcome measure
Hyperandrogenism: One blood sample was obtained at the beginning of the trial (baseline) and a second one was obtained at the end of the trial (9 months).

Secondary outcome measures

1. Hirsutism score. A medical control was performed monthly in order to evaluate hirsutism, and for adjusting insulin dose and check possible side effects. Clinical assessment of hirsutism with a visual scale, Ferriman-Gallwey score, was performed monthly.
2. Metabolic control. HbA1c assessment was performed every three months with blood obtained from capillary puncture of the fingers.
3. Ovulatory function. During the nine months protocol, the patients obtained a sample of capillary blood in a filter paper for measurement of progesterone levels and determine the presence of ovulation. The filter paper was obtained in days 18-23-28 of each menstrual cycle. The capillary blood sample was obtained together with the procedure of capillary blood puncture for measuring glucose levels, which the patients do every day.

Overall study start date
05/01/2005

Completion date
03/01/2008

Eligibility

Key inclusion criteria
1. Type 1 diabetes
2. Insufficient metabolic control
3. Clinical or biochemical hyperandrogenism
4. Already had menarche and younger than 22 yr

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
24

Key exclusion criteria
1. Type 2 or other type of diabetes.
2. Honeymoon period defined as an insulin daily requirement lower than 0.5 U/kg/day and HbA1c lower than 7%.
3. Diabetes duration less than 1.5 years
4. Abnormal thyroid function; elevated creatinine level
5. Use of contraceptive pills, steroids or any other type of medication
6. Presence of other chronic conditions

Date of first enrolment
05/01/2005

Date of final enrolment
03/01/2008

Locations

Countries of recruitment
Chile

Study participating centre
Casilla 226-3
Santiago
Chile
8360160

Sponsor information

Organisation
Scientific and Technological Development Fund (FONDECYT Fondo de Desarrollo Científico y Tecnológico) (Chile)

Sponsor details
Bernarda Morin 551
Providencia
Santiago
Chile
7500832

Sponsor type
Government

Website
http://www.conicyt.cl/fondecyt/

ROR
https://ror.org/02ap3w078

Funder(s)

Funder type
Government

Funder Name

Scientific and Technological Development Fund (FONDECYT Fondo de Desarrollo Científico y Tecnológico) (Chile) - Chilean government Grant number: 1050452

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/09/2009		No	No