Metformin treatment in adolescent patients with PCOS: A long-term, winning metabolic choice. Results from a single center 5-years retrospective clinical study

This study aimed to understand whether metformin therapy can improve insulin resistance in adolescent PCOS patients, both during treatment and after discontinuation, and to evaluate its action on the hormonal and metabolic pathways.

NCT number is not available.

A total of 168 patients participated in the study between 2015 and 2019. All participants were adolescents aged 12 to 17 affected by PCOS. Patients underwent OGTT and were divided into normoinsulinemic and hyperinsulinemic. Metformin therapy has been proposed for all hyperinsulinemic patients. Eighty patients were accepted and continued follow-up. Fifty-three patients did not receive metformin therapy and made up the control group. Patients in the metformin group had periodic follow-ups during and after the end of treatment. Controls similarly performed regular follow-ups.

Statistical analysis was performed using the IBM SPSS Statistics statistical software, version 26 (IBM SPSS Statistics, Chicago, IL, USA). Measurement data corresponding to the normal distribution were expressed by mean ± SD, and the t-test was used for the paired samples (Student's t-test). In addition, the count data were expressed as n (%), and the beta coefficient of linear regression with a 95% confidence interval (95% CI) was reported for each analysis. In all calculations, a p-value < 0.05 was considered significant.

The ethics committee of the University of Cagliari approved the study. All participants signed the informed consent for participation in the study.

Cagliari, 01/07/2015

UNIVERSITA' DEGLI STUDI DI CAGLIARI

FACOLTA' DI MEDICINA E CHIRURGIA

Metformin treatment in adolescent patients with PCOS: A long-term, winning metabolic choice. Results from a single center 5-years retrospective clinical study

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PURPOSE OF STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

This study aims to understand whether metformin therapy can improve insulin resistance in adolescent PCOS patients, both during treatment and after discontinuation, and to evaluate its action on the hormonal and metabolic pathways.

RISKS

Like all medicines, metformin can cause side effects, although not everyone gets them. These common side effects of metformin happen in more than 1 in 100 people.

Feeling sick (nausea)
Being sick (vomiting)
Diarrhea
Stomach ache
Loss of appetite
A metallic taste in the mouth
Metformin does not usually cause low blood sugar (known as hypoglicemia) when taken on its own. In rare cases, it is possible to have a serious allergic reaction (anaphylaxis) to metformin. Serious side effects are rare and happen in less than 1 in 10,000 people.

BENEFITS

Patients may improve their body mass index during treatment, lose weight, and improve their metabolic status due to better insulin sensitivity. This could also lead to a better androgen profile and corresponding clinical improvement.

PROCEDURE

The patients will be subjected to physical examination to evaluate hirsutism, according to the criteria of the Ferri and Gallwey score, as well as acne, using the Cremoncini classification.

Each patient will receive detailed advice on improving their lifestyle, such as physical activity and nutrition. We indications of the various food and their weighted intake and a balanced composition of macronutrients (carbohy 55%, lipids 25%, protein 20%; fiber ≥25 g/day), as recommended by the Reference intake levels of nutrients and energy for the Italian population (LARN) guidelines. Vegetables, fruit, cereals, fish, and pulses, typical of the Mediterranean style, are included in the diet.

We recommend ≥150 minutes per week of moderate or ≥75 minutes of vigorous-intensity exercise for weight ga prevention, minimizing sedentary time, and including strength training exercises for two days per week, as repor from the 2018 PCOS guideline.
Laboratory evaluations will be performed during the menstrual cycle's first follicular phase (days 3-7) and after a of 10-12 hours.

The following day, the patients undergo a 75 g oral glucose tolerance test (OGTT). Blood samples are collected and 60, 90, 120, and 180 min after ingesting 75 g of glucose in 150 ml of water. Insulin and glucose are assayed samples.

After about 24 months of treatment, the patients wll return to the hospital and repeat clinical and laboratory examinations.

CONFIDENTIALITY

Your responses to this study will be anonymous. Every effort will be made by the researcher to preserve your confidentiality including the following:

- Assigning code names/numbers for participants that will be used on all research notes and documents.
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

CONSENT

I have read and understand the provided information and have had the opportunity to ask questions. I know that my participation is voluntary and that I can withdraw at any time without giving a reason or without cost. I also declare that I have received detailed information regarding the study procedure, risks and benefits of this study, and my participation. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____