Metabolic and hormonal effects of Myoinositol and D-chiro-inositol the combined therapy with polycystic ovary syndrome (PCOS) patients (Myoinositol and D-chiro-inositol in PCOS)

First published: 28/09/2018

Last updated: 30/01/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25706

EU PAS number

EUPAS25705

Study ID

25706

DARWIN EU® study

No

Study countries

Poland

Study description

AbstractBackground. To evaluate the effects of the combined therapy with Myo-inositol (MI) and D-chiro-inositol (DCI) on hormonal and metabolic parameters of women with PCOS.Design. Prospective clinical study.Setting. PCOS patients in a clinical research environment.Patients. Seventy women diagnosed with PCOS according to Rotterdam criteria were enrolled in this study.Interventions. Patients received combined therapy of one tablet that contained 550 mg of inositol (myo-inositol (MI) and D-chiro-inositol (DCI) in a ratio of 10:1), 200 µg of folic acid, 500 IU of vitamin D, 0.7 mg of vitamin B6, 3 mg of vitamin B5, 1.25 µg of vitamin B12 twice a day for 6 months. At each visit, the body weight, height and BMI were all recorded, and serum levels of free testosterone (fT), sex hormone-binding globulin (SHBG), luteinizing hormone (LH), follicle-stimulating hormone (FSH) and glucose with insulin during standard OGTT (75 g) were all measured as well. Moreover transvaginal ultrasonography and skin condition assessment were performed at each visit. Results. Significant body weight reduction and decrease in fT, FSH, LH and insulin levels as well as significant increase of serum SHBG concentration were observed. Serum glucose levels during OGTT decreased after 6 months of treatment. Also skin conditions improved after just three months of treatment.Conclusions. Combination of MI and DCI in a ratio 10:1 seems to be efficient in improving both metabolic and hormonal parameters in PCOS patients.

Study status

Finalised

Research institutions and networks

Institutions

Center of Reproductive Health, Institute of Mother and Child, Warsaw

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/10/2014

Study start date

Actual: 08/01/2015

Data analysis start date

Actual: 20/09/2017

Date of final study report
Actual: 05/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Verco

Study protocol

Subjects and study design.pdf(49.32 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

Main study objective:

To evaluate the effects of the combined therapy with Myo-inositol (MI) and D-chiro-inositol (DCI) on hormonal and metabolic parameters of women with PCOS

Study Design

Clinical trial randomisation

Non-randomised clinical trial

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

INOSITOL

FOLIC ACID

PYRIDOXINE

VITAMIN D

VITAMIN B12

PANTOTHENIC ACID

Medical condition to be studied

Polycystic ovaries

Population studied

Short description of the study population

Women patients diagnosed with polycystic ovary syndrome (PCOS) according to Rotterdam criteria.

Age groups

Adults (18 to < 46 years)

Special population of interest

Other

Special population of interest, other

Polycystic ovary syndrome (PCOS) patients

Estimated number of subjects

70

Study design details

Outcomes

body weight reduction fT, FSH, LH and insulin levels serum SHBG Serum glucose levels during OGTT after 6 months of treatment

Data analysis plan

Quantitive data are presented as mean±SD. Wilcoxon test was used to determine whether the differences (both between the first and the second visit and between the first and the third visit) are statistically significant and a Bonferroni correction for multiple comparisons was applied. The significance level was set at 0.05/2=0.025. The percentage distribution was presented for qualitive data, such as skin condition, at the second and the third visit in relation to the first visit. To determine whether the data distribution differences

were statistically significant, the X2 test was used and when the expected frequency in any cell was less than 5 the Fisher's Exact Test was applied. The significance level was set at α=0.05.

Documents

Study results

Study results_EUPAS25705.pdf(51.23 KB)

Study publications

Carlomagno G, Nordio M, Chiu TT, Unfer V. Contribution of myo-inositol and mela…

Abdelhamid AM, Madkour WA, Borg TF. Inositol versus metformin administration in…

Artini PG, Di Berardino OM, Papini F, Genazzani AD, Simi G, Ruggiero M, Cela V…

Bevilacqua A, Carlomagno G, Gerli S, Montanino Oliva M, Devroey P, Lanzone A, S…

Nordio M, Proietti E. The combined therapy with myo-inositol and D-chiro-inosit…

Minozzi M, Nordio M, Pajalich R. The Combined therapy myo-inositol plus D-Chiro…

Data management

ENCePP Seal

Conflicts of interest of investigators

Alicja Jakimiuk28.09.2018coi_disclosure.pdf(1.2 MB)

Artur Jakimiuk28.09.2018coi_disclosure.pdf(1.2 MB)

Marcin Januszewski28.09.2018coi_disclosure.pdf(1.2 MB)

Santor-Zaczyńska28.09.2018coi_disclosure.pdf(1.2 MB)

Tadeusz Issat28.09.2018coi_disclosure.pdf(1.2 MB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown