

Ovulation induction in women with newly diagnosed polycystic ovary syndrome: a randomised double blind clinical trial comparing clomiphene citrate plus metformin with clomiphene citrate plus placebo

Submission date

27/01/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

27/01/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

04/04/2013

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR485

Study information

Scientific Title

Acronym

The Metformin trial

Study objectives

To compare the effectiveness of clomiphene citrate with metformin versus clomiphene citrate only in women with newly diagnosed polycystic ovary syndrome with respect to ovulation, pregnancy and spontaneous abortions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Polycystic Ovary Syndrome (PCOS)

Interventions

1. Metformin 4 dd 500 mg plus clomiphene citrate 50 - 150 mg
2. Control: placebo 4 dd plus clomiphene citrate 50 - 150 mg

Patients used the medication as long as they were participating in the study. They stopped taking medication when they were clomiphene citrate resistant, pregnant or dropped out for a different reason.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Clomiphene citrate, metformin

Primary outcome measure

Ovulation.

Secondary outcome measures

1. Ongoing pregnancy
2. Spontaneous abortion
3. Clomiphene citrate resistance

Overall study start date

01/06/2001

Completion date

01/06/2004

Eligibility**Key inclusion criteria**

All patients with chronic anovulation World Health Organization (WHO) type II, polycystic ovaries diagnosed by transvaginal ultrasonography and child wish.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

228

Key exclusion criteria

1. Other causes of anovulation
2. Age over 40 years and liver, kidney or heart disease/failure (i.e. abnormal results on liver function tests)

3. Serum creatinine concentration greater than 95 $\mu\text{mol/l}$ or a history of heart disease/failure)
4. Sperm quality indicating male factor subfertility (total motile count less than 10×10^6)

Date of first enrolment

01/06/2001

Date of final enrolment

01/06/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Center (AMC) (The Netherlands)

Sponsor details

Department of Obstetrics and Gynaecology

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Industry

Funder Name

Merck B.V. (The Netherlands)

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?
Results article	results	24/06/2006		Yes	No
Results article	results	01/11/2012		Yes	No