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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

Registration date
27/01/2006

Overall study status
Completed

Last Edited
04/04/2013

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Etelka Moll

Contact details
Academic Medical Center
Department of Obstetrics & Gynecology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
E.Moll@amc.uva.nl

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Ovulation.

Key secondary outcome(s)
1. Ongoing pregnancy
2. Spontaneous abortion
3. Clomiphene citrate resistance

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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 umol/l or a history of heart disease/failure)
4. Sperm quality indicating male factor subfertility (total motile count less than 10 x 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)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Merck B.V. (The Netherlands)

Results and Publications

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