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Use of PDE inhibitors for endometrial growth

Submission date
28/07/2015

Recruitment status
No longer recruiting

Registration date
11/08/2015

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The objective of this study is to assess the impact of the drug tadalafil on endometrial growth (growth of the inner lining of the uterus, or womb), and blood flow to and from the uterus (measured by uterine artery pulsatility (PI)) and resistance index (RI)) in female patients being treated for infertility with clomiphene in order to encourage ovulation.

Who can participate?
Infertile female patients aged between 18-42 taking clomiphene to encourage ovulation.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are placed in cycle A. They are treated with 100mg clomiphene citrate per day from day 2 to day 6 of the cycle and 5mg tadalafil per day from the 4th day to the 10th day of the cycle. Those in group 2 are placed in cycle B. These participants are treated only with the 100mg clomiphene citrate per day from day 2 to day 6 of the cycle. After being treated in cycle A or B, all participants are then reallocated to the other cycle and treated accordingly. Endometrial growth, PI and RI are assessed for all participants on day 4, 8 and 12 of each cycle.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The Zambrano Hellion Medical Center, Monterrey Institute of Technology (Mexico)

When is the study starting and how long is it expected to run for?
September 2014 to August 2015

Who is funding the study?
1. Monterrey Institute of Technology and Higher Education (Tecnológico de Monterrey) (Mexico)
2. CREASIS - Assisted Reproduction Center (Mexico)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
PDE inhibitors and endometrial growth under clomiphene ovarian stimulation

Study objectives
1. Long lasting phosphodiesterase inhibitors decreases the uterine artery pulsatility index on clomiphene ovarian stimulation
2. Long lasting phosphodiesterase inhibitors improve the endometrial growth on clomiphene ovarian stimulation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee, 27/08/2013, ref: IPDE5EC

Primary study design
Interventional

Study design
Randomised single centre cross over study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infertility. Poor endometrial growth.

Interventions

Patients will be randomized according to previously sealed envelopes in order to start with Cycle A or Cycle B.

1. Cycle A: patients will receive clomiphene citrate 100 mg/day from the 2nd to the 6th day of the cycle and also tadalafil 5 mg/day from the 4th day to the 10th day of the cycle.
2. Cycle B (control): patients will only receive clomiphene citrate 100 mg/day from the 2nd to the 6th day of the cycle.

All patients will be monitored until the evidence of clinical pregnancy by ultrasound.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
Endometrial growth, using ultrasound scans at day 4, 8 and 10.

Key secondary outcome(s)
1. Uterine artery pulsatility index
2. Uterine artery resistant index

Measured by ultrasound on Day 4, 8 and 10.

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Infertile patients candidates to clomiphene ovarian stimulation
2. Female
3. 18 to 42 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Smoking
2. Arterial hypertension
3. Prior uterine surgery

Date of first enrolment
01/09/2014

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
Mexico

Study participating centre
The Zambrano Hellion Medical Center, Monterrey Institute of Technology (Centro Medico Zambrano Hellion. Tecnológico de Monterrey)
Batallón de San Patricio 112
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Sponsor information

Organisation
Tecnológico de Monterrey. Centro Médico Zambrano Hellion.

ROR
https://ror.org/03ayjn504

Funder(s)

Funder type
University/education

Funder Name
Monterrey Institute of Technology and Higher Education (Tecnológico de Monterrey)

Funder Name
CREASIS - Assisted Reproduction Center (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/12/2015	22/01/2019	Yes	No