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Establishment of new index for prediction of the implantation success rate, combining the endometrial thickness, the size of the uterus and their ratio

Submission date
18/10/2016

Recruitment status
No longer recruiting

Registration date
21/11/2016

Overall study status
Completed

Last Edited
07/11/2016

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Infertility is a growing problem worldwide. For some couples, the only way to get pregnant is to undergo fertility treatment such as by in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI). In these treatments, eggs are taken from women and fertilized outside of the body to create an embryo and then returned to the woman's womb to develop. In order to give the embryo the best possible chance of attaching to the lining of the womb and developing into a baby, the thickness of the womb lining (endometrium) is measured. Many studies show that there is a relationship between the thickness of the endometrium and the successful pregnancy rate. There is strong evidence also, that in ladies with small wombs, the endrometrium can be thinner and the woman still becomes pregnant. The aim of this study is to combine information about thickness of the endometrium and womb size in order to better predict pregnancy after IVF/ICSI.

Who can participate?
Women aged between 20 and 45 who are undergoing fertility treatment by IVF or ICSI in Vienna In Vitro Center.

What does the study involve?
During routine follow ups after undergoing IVF/ICDI, women have a transvaginal ultrasound on day 2-3, 6-8 and 10-11 of their cycle. This involves having an ultrasound probe placed into the vagina in order to measure the thickness of the endometrium and womb size. Participants have a blood test 10-13 days after the embryos are implanted to see if they are pregnant which is further confirmed by another transvaginal ultrasound after 20-25 days.

What are the possible benefits and risks of participating?
There are no benefits for the patients, except the feeling that they are helping with the

advancement of science and improving future services. There are virtually no additional risks for the patients, because the measurements taken are used routinely for the purpose of the IVF /ICSI treatment.

Where is the study run from?
Vienna In Vitro Center (Bulgaria)

When is the study starting and how long is it expected to run for?
June 2016 to December 2017

Who is funding the study?
Vienna In Vitro Center (Bulgaria)

Who is the main contact?
Dr Georgi Stanulov

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Establishment of new index for prediction of the implantation success rate, combining the endometrial thickness, the size of the uterus and their ratio: Prospective analyse in 100 IVF/ICSI cycles

Study objectives
Females present with an inborn variety of uterine size and the uterine size gives a certain limit to the maximum thickness of the endometrium. Measuring the endometrium thickness and its

evaluation in combination with the uterine size it is possible to better predict the IVF/ICSI success rate, than using the endometrium thickness measurement alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Ethic committee of MBAL "Tokuda" Sofia Bulgaria

Study design
Prospective cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Sterility treatment

Interventions
During the routine follow up in their IVF/ICSI cycle, women undergo a transvaginal ultrasound on day 2-3, 6-8 and 10-11 of the cycle. The duration of the ultrasound exam is about 10 minutes and the measurement of the Anterior-posterior dimension of uterine corpus/endometrium thickness takes about one minute.
During the transvaginal ultrasound exam endometrium thickness and uterine size will be measured.

Participants undergo blood testing 10-13 days after embryo transfer to prove biochemical pregnancy and another ransvaginal ultrasound on the day 20-25 after the embryo transfer to prove clinical pregnancy.

Intervention Type

Primary outcome(s)
1. Endometrium thickness is measured using transvaginal ultrasound before the start of an IVF /ICSI cycle, and then on day 2-3, 5-8 and 9-11 of the IVF/ICSI cycle.
2. Uterine size is measured using transvaginal ultrasound before the start of an IVF/ICSI cycle, and then on day 2-3, 5-8 and 9-11 of the IVF/ICSI cycle

Key secondary outcome(s)
IVF/ICSI success rate is measured using βhCG on 10-13 day after the embryo transfer (to prove biochemical pregnancy) and transvaginal ultrasound on the day 20-25 after the embryo transfer (to prove clinical pregnancy).

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Women
2. Undergoing fertility treatment by stimulated IVF/ICSI, using the Antagonist Protocols
3. Transfer done on day 5 after the ovum pick up
4. Aged 20-45 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Large or multiple fibroids
2. Uterine anomalies
3. Extremely small uterus APDUC bellow 25mm
4. BMI outside the range 19 - 29

Date of first enrolment
01/12/2016

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Bulgaria

Study participating centre
Vienna In Vitro Center
Tokuda Hospital Sofia, IX floor
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Sponsor information

Organisation
Vienna In Vitro Center

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vienna In Vitro Center

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated duringthe current study are not expected to be made available due to very personal character of the procedures and because of patient requests.

IPD sharing plan summary
Not expected to be made available