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Comparison of pregnancy rates following transfer of one embryo versus two in patients under going fertility treatment

Submission date
30/12/2011

Recruitment status
No longer recruiting

Registration date
15/03/2012

Overall study status
Completed

Last Edited
23/01/2014

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
Couples trying to start a family sometimes encounter difficulties in fulfilling the dream. In-vitro fertilization and embryo transfer (IVF-ET) (test tube baby) was introduced 30 years ago. It has since helped many infertile couples in enjoying parenthood. Over the last 20 years the results of IVF-ET have improved dramatically, but the risk of multiple pregnancies has also increased. There is now a trend among infertility specialists to transfer fewer embryos to reduce the occurrence of multiple pregnancies. Over the last 10 years most infertility clinics have transferred only two embryos in women who are less than 35 years old. Physicians in many European countries and in some clinics in North America have been transferring one embryo in certain patients without reducing pregnancy chances. The aim of this study is to decrease the occurrence of multiple pregnancies without decreasing the chances of getting pregnant. In this study we will compare the chances of pregnancy, miscarriage, delivery and multiple pregnancies between two groups of participating patients. This is to determine if transferring only one embryo would affect your chances of getting pregnant compared to transferring two embryos. The embryos will be transferred back to your womb five days after obtaining the eggs at a stage of embryo development called the blastocyst stage, providing the blastocysts are of good quality.

Who can participate?
You are eligible for this study if you are infertile, no matter what the reason is for your infertility. You need to be 18-35 years old with a good supply of eggs, as determined by certain blood tests, and without problems in your womb that could interfere with pregnancy. In addition, you should not have undergone more than two failed IVF-ET cycles in the past.

What does the study involve?
During this study you and all other participants will receive the same treatment (fertility medications) to get you to produce several eggs, which will be retrieved from your uterus by a simple surgery after you have been given medication to help you fall asleep very briefly. Your eggs will be fertilized with your partners sperm and the embryos will be observed in the laboratory for five days. If two or more of your embryos reach the blastocyst stage and are of

good quality, you will continue with the study. Otherwise, you will be dropped out of the study and the number of embryos to be transferred to you will depend on the quality of your embryos and your particular situation. This will be determined by the physician performing your embryo transfer after consulting with you and your partner. If you continue with the study, you will be randomly assigned to one of two groups. If you are in group 1 you will have one blastocyst transferred back to the uterus. If you are in group 2 you will have two blastocysts transferred. After two weeks a pregnancy test will determine whether you are pregnant or not. If you are pregnant, an ultrasound scan will be done two weeks after your positive pregnancy test to determine if the pregnancy is good and to see if there is more than one baby. A second ultrasound scan will be done after one to two weeks and after that you will be transferred to the care of you obstetrician.

What are the possible benefits and risks of participating?
There are no direct benefits from participating in the study. However, patients participation may help in the advancement of science by finding out the benefit of avoiding multiple pregnancies with all its obstetric, neonatal, developmental and financial consequences. The sponsor, Ferring Pharmaceuticals, Inc., is partially providing medications in addition to a limited grant that helps to off-set some of the costs related to the study and also helps to reduce the cost to you for undergoing a cycle of IVF-ET. Some studies say that the chances of pregnancy after the transfer of only one blastocyst may be decreased by 5-10%. Other studies say that the chances of getting pregnant will not be decreased. In fact, the American Society of Reproductive Medicine recommends transferring one blastocyst in favorable circumstances. There are often potential risks and complications associated with IVF in general. Those risks and complications are listed in the consent form. The risks of those procedures are detailed especially in the IVF-ET consent forms, including the consent form for ovarian stimulation, consent form for in vitro fertilization and consent form for embryo transfer.

Where is the study run from?
Hurley Medical Center (MI, USA).

When is study starting and how long is it expected to run for?
The study ran from October 2008 to November 2013.

Who is funding the study?
The study is sponsored by Ferring Pharmaceutical Company. The company will be partially providing you with the medications you need while going through IVF. In addition, IVF Michigan is offering you a 50% discount on the cost of the procedure.

Who is the main contact?
Sheryl Benford-Loyer, RN
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
190454-4

Study information

Scientific Title
Comparing the results of one blastocyst transfer versus two in good prognosis patients going through in vitro fertilisation (IVF) with intra cytoplasmic sperm injections (ICSI) and embryo transfer (ET): a prospective, randomized study.

Study objectives
Null hypothesis: no statistical difference in pregnancy rates between the transfer of one blastocyst versus two blastocysts.

On 23/01/2014 the anticipated end date was changed from 29/08/2012 to 02/11/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hurley Medical Center Institutional Review Board, 28/10/2008 (reviewed 30/08/2011), ref: 190452-4

Study design
Prospective randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infertility

Interventions

Patients are randomised to either one of the two groups:
1. Receive one embryo
2. Receive two embryos

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Pregnancy rate

Key secondary outcome(s))
1. Implanation rate
2. Delivery rate
3. Miscarriage rate

Completion date
02/11/2013

Eligibility

Key inclusion criteria
1. Patients going through a cycle of IVF/ET
2. Have signed a consent form
3. Age 18 - 35 years old
4. Follicle-stimulating hormone (FSH) level on cycle day 2 or 3 < 10

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Day 2 or 3 FSH level > 10
2. Previous history of poor response to stimulation drugs
3. Previous history of more than one failed IVF cycle

Date of first enrolment
28/10/2008

Date of final enrolment
02/11/2013

Locations

Countries of recruitment
United States of America

Study participating centre
Hurley Medical Center
Flint
United States of America
MI 48532

Sponsor information

Organisation
Hurley Medical Center (USA)

ROR
https://ror.org/034npj057

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
IVF Michigan (USA)

Funder Name
Ferring Pharmaceuticals Inc (USA)

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	01/11/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes