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TRansvaginal Ultrasonography versus Saline sonography Trial in patients having their IVF treatment - TRUST-IVF study

Submission date
25/05/2012

Recruitment status
No longer recruiting

Registration date
16/08/2012

Overall study status
Completed

Last Edited
14/08/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
In vitro fertilisation (IVF) is a technique used to help people with fertility problems to have a baby. Before undergoing IVF, the shape of the woman's uterine cavity (the space inside the uterus) must be checked for abnormalities. The detection and treatment of uterine cavity abnormalities can increase the success rate of IVF treatment. A 2-D transvaginal ultrasound scan (2-D TVS) is a simple tool for finding uterine cavity abnormalities. It involves scanning with an ultrasound probe placed inside the vagina. Saline infusion sonography (SIS) is a test where a small volume of saline (salt solution) is inserted into the uterus to allow the lining of the uterus to be clearly seen on an ultrasound scan. We can obtain more information about the uterine cavity from SIS. The aim of this study is to find out whether performing a SIS before starting an IVF cycle improves the likelihood of achieving a live birth, compared with the use of 2-D TVS.

Who can participate?
Women under the age of 40 and undergoing their first or second IVF treatment cycle.

What does the study involve?
All participants undergo a 2-D TVS. If the initial scan is normal, the participants are then randomly allocated to undergo either SIS or another 2-D TVS before commencing their IVF treatment. After 12 months the number of live births in both groups is recorded.

What are the possible benefits and risks of participating?
Using SIS may increase the chances of finding and treating uterine cavity abnormalities. There is a minimal risk of infection and pain with SIS. However, this risk is minimised with infection screening and taking analgesia (painkillers) before the procedure.

Where is the study run from?
The Assisted Conception Unit at Guy's Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2012 to June 2015

Who is funding the study?
The Assisted Conception Unit at Guy’s Hospital (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial comparing Transvaginal Ultrasonography versus Saline sonography Trial in patients having their IVF treatment - TRUST-IVF study

Acronym
TRUST-IVF

Study objectives

The pregnancy rate in the SIS group is no different to pregnancy rate in the 2-D transvaginal ultrasound scan (2-D TVS) control group. The alternative hypothesis is that pregnancy rate in the Saline sonography (SIS) group is equal to or higher than pregnancy rate in the control group.

The evaluation of the shape and regularity of the uterine cavity is one of the basic steps in the workup of infertile couples before in vitro fertilisation (IVF). Uterine cavity abnormalities have been reported to be more prevalent in subfertile women and are estimated to be the etiologic factor in as many as 10-15% of couples seeking treatment.The detection and treatment of these intrauterine pathologies can potentially increase the success rates of IVF treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee London- Riverside ; South west Research Ethics Committee, Bristol, 17/01 /2012, ref: 11/LO/1591

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
In vitro fertilisation (IVF)

Interventions
All women recruited for the trial will undergo a 2-D TVS. If the initial scan is normal, the participants will then undergo randomisation to receive SIS or another 2-D TVS before commencing their treatment.

Saline infusion sonography arm : A SIS is a well-tolerated internal examination that uses a fine catheter, which is passed through the cervix by initially performing a speculum examination. A small amount of saline (5-10 ml) is passed through the catheter and a transvaginal scan is performed at the same time to examine the lining and shape of the womb cavity. The procedure usually takes approximately 10 minutes to complete. After the scan, if there are any abnormalities identified, the patient will be listed for surgery to have the abnormality removed.

Transvaginal scan: A transvaginal scan is an internal scan which is routinely performed as a part of the infertility investigations. The patient will be asked to empty their bladder and lie down on a couch with the legs on stirrups. A doctor or nurse will perform the transvaginal scan.They will be taking measurements of the uterus and ovaries and any other additional pathology. This procedure should take no longer than 10 minutes.

The follow up for all the treatment arms is 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Livebirth rate

Secondary outcome measures
1. Clinical pregnancy rate
2. Implantation rate
3. Uterine anomaly rate

Overall study start date
15/06/2012

Completion date
15/06/2015

Eligibility

Key inclusion criteria
1. Women undergoing their first and second IVF/ ICSI (Intra Cytoplasmic Sperm Injection) treatment
2. Women under the age of 40 and undergoing their first or second IVF cycle will be eligible to participate in the trial

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
792

Key exclusion criteria
1. Women aged more than 40 years (women aged 41 years or more).
2. Known submucous fibroids, polyps, intrauterine adhesions or uterine surgery

3. Untreated Hydrosalpinges (women whose hydrosalpinges have been treated with clipping, salpingectomy or ligation will be included)
4. Recurrent implantation failure defined as patients undergoing three or more IVF cycles

Date of first enrolment
01/07/2012

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's Hospital (UK)

Sponsor details
Assisted Conception Unit
Tower Wing
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/04r33pf22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's Hospital - Assisted Conception Unit (UK)

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