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The use of seminal plasma in IVF

Submission date
23/11/2016

Recruitment status
No longer recruiting

Registration date
24/11/2016

Overall study status
Completed

Last Edited
05/02/2020

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
There is a suggestion that seminal plasma (seminal fluid with no sperm) may play a role in the egg implanting into the womb. In patients undergoing fertility treatment to help them have a baby, such as in-vitro fertilization (IVF) or intra-cytoplasmatic injection (ICSI), seminal fluid does not come into contact with the womb, as embryos are transferred without seminal plasma and patients usually abstain (or advised to abstain) from sexual intercourse for several days both before and after egg retrieval. Seminal fluid contains several proteins that interact with cells in the endometrium (lining of the womb) to induce a cascade which activates maternal immune activity to accept the 'invading' embryo. Animal and human studies have suggested that when participants are inserted with seminal plasma during fertility treatment they have higher levels of conception in comparison to their controls. The aim of this study is to investigate whether seminal plasma injected into the uterine cavity during fertility treatment improves clinical pregnancy rates.

Who can participate?
Patients aged between 23 and 39 years old undergoing IVF at the Homerton Fertility Centre who are undergoing their first or second cycle of IVF using their partner’s fresh sperm for their IVF cycle and not sperm that has been frozen or that comes from a donor.

What does the study involve?
Participants are randomly allocated to one of two groups on the day that eggs are collected from the woman to fertilise with her partner's sperm to create an embryo in the lab. As usual procedure the male partner’s sperm will be separated from the seminal fluid in the laboratory. Usually the remaining fluid will be discarded by the embryologist. However, for this researches purpose they will not be discarded. After egg collection, if the patient is in the first group they receive 0.5 ml of their partner's seminal fluid by injection into their womb. Those in the other group receive a 0.5 ml injection of placebo (dummy) fluid. This procedure takes less than 2-3 minutes. Treatment before and after the day of egg collection is completely routine. One month after the study, pregnancy results are recorded.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Homerton Fertility Centre (UK)

When is study starting and how long is it expected to run for?
July 2013 and October 2015

Who is funding the study?
Homerton Fertility Centre (UK)

Who is the main contact?
Dr Giselle Crawford
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of intrauterine injection of seminal plasma on IVF results: A prospective double-blind randomized placebo-controlled trial

Study objectives
There is improved clinical pregnancy and live birth rates when patients are exposed to seminal plasma at the time of oocyte pickup during an IVF cycle.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – South East REC, 03/02/2014, ref: 13/LO/1835

Study design
Single-centre prospective double-blind randomised placebo-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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Infertility requiring in vitro fertilisation for its management

Interventions
Participants are randomized on the day of oocyte pick-up to one of two groups with the use of a computer-generated random number sequence and opaque sealed envelopes by the lead Embryologist. On the morning of the scheduled oocyte aspiration, opaque sealed envelopes are opened consecutively by the lead Embryologist. Once prepared, the blinded sample is transferred to the operating theatre by the Embryologist and handed to the physician for intrauterine injection.

Intervention group: Participants receive 0.5µL aliquot of their partner's seminal plasma injected into their uterine cavity at the time of their scheduled oocyte pick-up.

Control group: Participants receive 0.5µL of Quinn's Sperm Wash Media (Sage Origio, Måløv, Denmark) injected into their uterine cavity at the time of their scheduled oocyte pick-up.

The follow up for trial participants is routine as for any patient undergoing an IVF cycle within the unit. It includes a serum pregnancy test two weeks after oocyte pickup and if this was positive a pelvic ultrasound is performed five weeks after oocyte pickup. All patients undergoing fertility treatment in our centre routinely have their live birth data collated by the unit.

Intervention Type
Biological/Vaccine

Primary outcome measure
Clinical pregnancy rate (CPR) is assessed via pelvic ultrasound at 7-8 weeks gestation.

Secondary outcome measures
1. Miscarriage rate is measured by pelvic ultrasound at 7-8 weeks gestation
2. Multiple pregnancy rate is assessed via pelvic ultrasound at 7-8 weeks gestation
3. Live birth rate (LBR) is determined through medical record review at three months after the expected date of delivery (routinely collected for all patients undergoing fertility treatment within the unit)

Overall study start date
01/07/2013

Completion date
31/10/2015

Eligibility

Key inclusion criteria
1. Patients undergoing IVF or ICSI treatment at the Homerton University Hospital, London, between February 2014 and September 2014
2. Female partner aged 23-39 years and with any cause infertility

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Total final enrolment
186

Key exclusion criteria
1. The couple having undergone a prior cycle with failed fertilization
2. The use of donor oocytes or frozen-thawed sperm
3. The presence of hepatitis B, hepatitis C, or HIV infections; leucospermia or other signs of infection
4. Men with <500 µl of SP
5. Enrollment in conflicting studies

Date of first enrolment
03/02/2014

Date of final enrolment

31/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Homerton Fertility Centre
Homerton Row
Homerton
London
United Kingdom
E96SR

Sponsor information

Organisation
Homerton Fertility Centre

Sponsor details
Homerton University Hospital
London
England
United Kingdom
E96SR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00x444s43

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Homerton Fertility Centre

Results and Publications

Publication and dissemination plan
The preliminary results of this study were presented at the RCOG (Royal College of Obstetrics & Gynaecology) World Congress in Brisbane Australia in April 2015. Plans to submit the paper including the live birth results to Human Reproduction for publication.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Giselle Crawford (giselle.crawford@health.nsw.gov.au)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at the RCOG/RANZCOG Congress	01/04/2015	05/02/2020	No	No
HRA research summary			28/06/2023	No	No