

# The use of seminal plasma in IVF

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| <b>Submission date</b><br>23/11/2016   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>24/11/2016 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>05/02/2020       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> 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-cytoplasmic 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  
giselle.crawford@health.nsw.gov.au

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Giselle Crawford

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## Additional identifiers

**Protocol serial number**  
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

## Study type(s)

Treatment

## 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(s)

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

## Key secondary outcome(s)

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)

## 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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  $\mu$ l 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**

United Kingdom

England

**Study participating centre****Homerton Fertility Centre**

Homerton Row

Homerton

London

United Kingdom

E96SR

# Sponsor information

## Organisation

Homerton Fertility Centre

## ROR

<https://ror.org/00x444s43>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Homerton Fertility Centre

# Results and Publications

## 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](mailto: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? |
|--------------------------------------|--|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a>     | results presented at the RCOG/RANZCOG Congress | 01/04/2015   | 05/02/2020 | No             | No              |
| <a href="#">HRA research summary</a> |  |              | 28/06/2023 | No             | No              |