

The HABSelect Trial: ‘Increasing live births and reducing miscarriages’

Leicester Fertility Centre is currently taking part in a large multicentre UK trial which currently has 13 clinics taking part.

The trial aims to find out whether using a new way to select sperm for ICSI can improve the chance of a successful pregnancy and/or reducing the chance of miscarriage.

Why is the trial taking place?

Intra-Cytoplasmic Sperm Injection (ICSI) refers to the technique of injecting a single sperm into the egg. This overcomes any barriers that the sperm has to get into the egg and is particularly beneficial in couples with severe male factor infertility or those who have had a previous failure of fertilisation in an IVF cycle. The embryologist chooses the best sperm by appearance before injecting it into the egg. This bypasses the normal process where the egg itself selects the successful sperm for fertilisation.

ICSI is very successful at achieving fertilisation of the egg, however, it is estimated that less than a quarter of all fertilised eggs, will result in a live birth. The reasons for this are not obvious but evidence suggests that we are still not very good at choosing the best sperm for injection.

Previous studies on sperm show that some immature or damaged sperm have higher rates of damage to their genetic material (DNA). These sperm then can't develop vital proteins that help the sperm bind to a substance called Hyaluronan (HA). HA is found in many places in the body and it is particularly concentrated on the surface of human eggs. Normal sperm bind to this substance and can then get into the egg, which results in fertilisation.

What are the aims of the trial?

The HAB (Hyaluronan binding) Select study will look at the differences between sperm that can bind to HA and sperm that cannot. A specialised 'PICSI' dish, which has dots of HA on it, will be used. This dish lets us pick out the sperm that bind to HA (and are therefore normal) so that we can use them for ICSI treatment.

Can we take part in the trial?

If you are having ICSI treatment then you will probably be asked if you are happy to take part in this trial. There are a few restrictions. We will ask you both to read some patient information and sign extra consent forms.

Couples involved in the trial will be selected randomly to either:

- The Intervention Group – where the embryologist will select the sperm using HA binding for the ICSI procedure.

Or

- The Non-Intervention (Control) Group – where the embryologist will select the sperm by looking at the appearance of the sperm (the standard way) for the ICSI procedure.

Either way, from your point of view, the process through treatment will be exactly the same for both groups. The only difference will be the way that we select your sperm for your ICSI.

You will not be able to find out which group you have been placed into until the trial has ended (in approximately 3-4 years time).

Is it safe?

Yes, we are only testing sperm selection methods for the ICSI procedure. The specialised PICSI dishes have been thoroughly safety tested, are MHRA approved and has obtained all necessary approval for clinical use within European Union (EU). All other parts of the ICSI procedure remain the same as in the standard practice, as does the way your treatment is followed up afterwards. The studies that have been done so far do not show any signs that your treatment is likely be compromised by you taking part.

What do we do now?

We encourage you to join the trial, if you are eligible. Please ask your nurse/embryologist/doctor about the trial next time you are in the clinic and they will be happy to answer any questions you have.

However, if you think this isn't for you then there is no pressure or obligation to take part.

How can we find out more?

Please visit the HABSelect website at:

<http://www.habselect.org.uk/>