merrion
FERTILITY CLINIC

PICSI

Physiological intracytoplasmic sperm injection

Reception: +353 1 556 7900

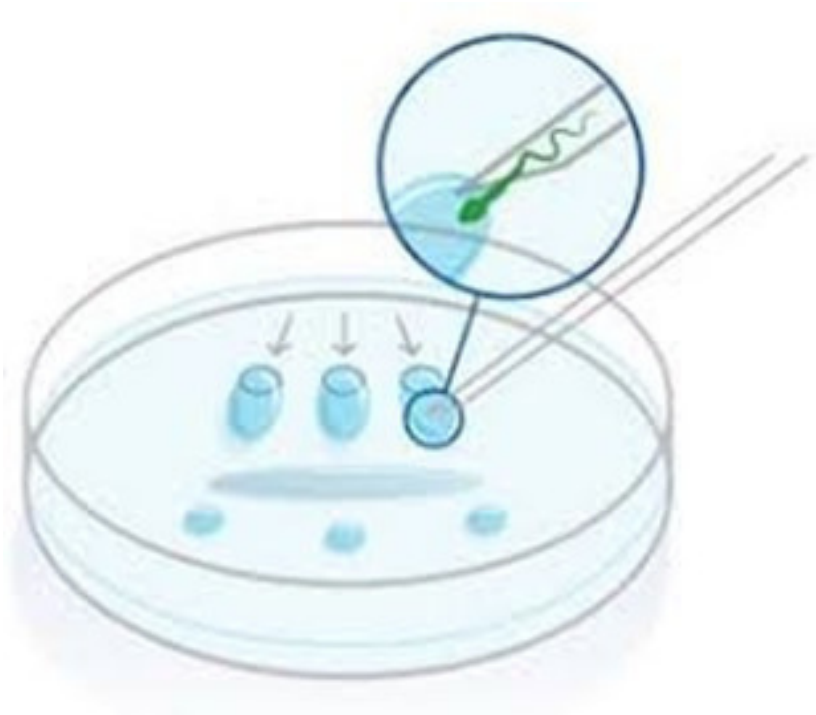
Information about the study

Intracytoplasmic Sperm Injection (ICSI) involves directly injecting an egg with a selected sperm. In standard ICSI, sperm to be injected are selected by the embryologist. The embryologists aim to select sperm that have good morphology (normal appearance) and good motility (moving progressively). Physiological Intracytoplasmic Sperm Injection (PICSI) is a type of ICSI, involving selection of sperm according to their ability to bind to hyaluronan or hyaluronic acid (HA). Hyaluronan is a naturally occurring biopolymer found in all human cells, including eggs. Mature, biochemically competent sperm bind to HA around the egg.

The PICSI® dish, a CE marked medical device, produced by Cooper Surgical contains dots of a HA hydrogel. PICSI allows the embryologists to select normal looking sperm that bind to HA. There is some evidence to show that PICSI improves reproductive outcomes, compared to standard ICSI, particularly where the female partner is over the age of 35 years.

The researchers at Merrion Fertility Clinic hope to study the effect of PICSI vs standard ICSI on fertility treatment outcomes for couples who are undergoing ICSI treatment by comparing outcomes from a sibling cohort of eggs (eggs collected from one egg collection on one woman).

.



Sperm selection after binding to HA in PICSI® dish.

Who is organising and funding this study?

This study is being organised by the research team at Merrion Fertility Clinic. The cost of the PICSI® dishes will be covered by the clinic.

Why am I being asked to take part?

You are being asked to participate as you are attending Merrion Fertility Clinic for ICSI treatment. You must meet the following inclusion criteria:

1. Scheduled for an ICSI cycle using your own eggs and sperm
2. Negative viral screen
3. Negative chlamydia screen
4. Capacity to understand protocol and give informed consent
5. Female age >35 years and/or male age >40 years
6. Have a minimum of two mature eggs at time of egg maturity assessment

How will this study be carried out/ what will happen to me?

If you agree to take part in this study, on the day of the egg collection and production of a sperm sample, mature eggs collected will be randomly divided into two groups. Half of the eggs will be injected with sperm selected by PICSI and the other half of the eggs will be injected by sperm selected with standard ICSI. Fertilisation and embryo development will be monitored as normal. You will be informed of the number of fertilised eggs and how your embryos are developing, as normal. Embryos of a certain quality may be suitable for transfer or to freeze. The decision on whether embryos are suitable for transfer or freezing will not be impacted by whether they are from the PICSI or standard ICSI group. Your medical records will be accessed by researchers and relevant details will be recorded.

What are the risks?

There are no known risks associated with this study.

Is this study confidential?

All results measured will be completely confidential. Data will be coded and anonymized. You will be given a study number, only the research team, overseen by the data controller (Dr Louise Glover, Head of Research, Merrion Fertility Clinic) will have access to your name and contact details in relation to this study. You are free to decide whether to take part in this research study and you can withdraw your consent at any time.

Data protection

Merrion Fertility Clinic and our research team have strict protocols in place to avoid any data protection issues. All data is stored on a secure, password-protected server at Merrion Fertility Clinic. Your personal data will not leave Merrion Fertility Clinic. You have a right to withdraw consent at any time by contacting the research team at Merrion Fertility Clinic.

Who has approved this study?

This study has been approved by the research ethics committee of the National Maternity Hospital.

If I want more information?

You may wish to discuss participation in this research project with Merrion Fertility Clinic.
If more information is required, please contact Merrion Fertility Clinic at: research@merrionfertility.ie

Thank you for taking the time to read this information leaflet and for your consideration to participate in this important research project.

Principal Investigator's name: Dr David Crosby, MD
Principal investigator's title: Clinical Director, Consultant Gynaecologist
Data Controller's/joint Controller's Identity: Dr Louise Glover, PhD
Data Controller's Contact Details: research@merrionfertility.ie
Data Protection Officer's Identity: Jessica Quinn
Data Protection Officer's Contact Details: jquinn@merrionfertility.ie