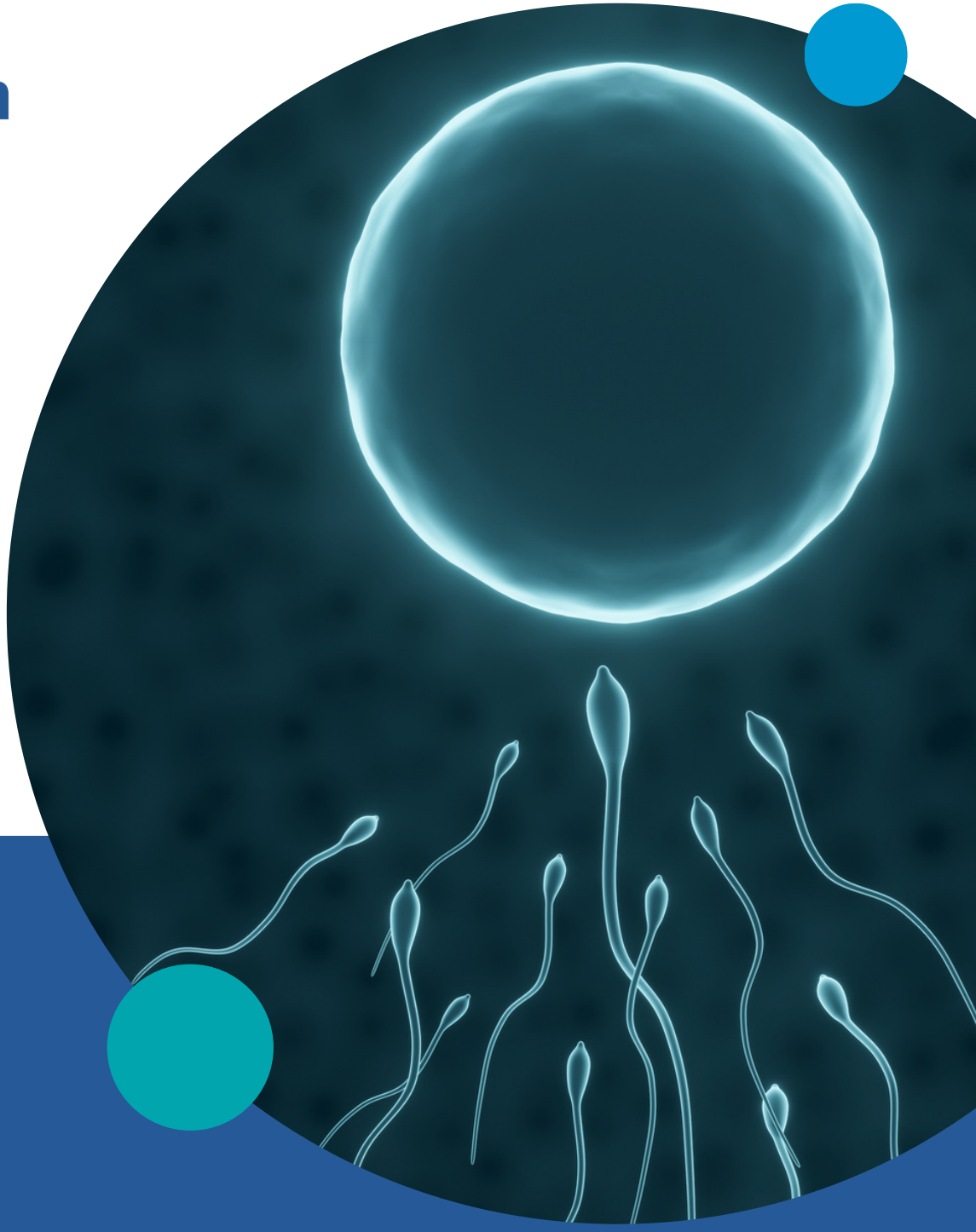
merrion
FERTILITY CLINIC



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).

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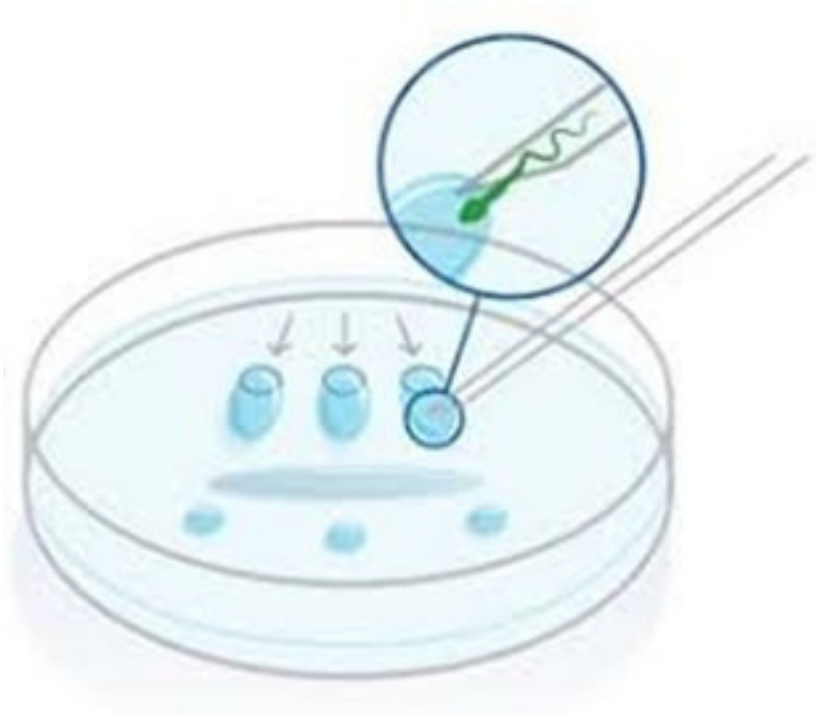

Sperm selection after binding to HA in PICSI® dish.

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 collectedwill 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 informedof the number of fertilised eggs and how your embryosare developing, as normal. Embryos of a certain qualitymay be suitable for transferor to freeze. The decisionon whether embryos are suitable for transfer or freezing will not be impacted by whether they are from the PICSIor standard ICSI group. Your medical recordswill be accessedby 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.

Principalinvestigator's name: Dr David Crosby, MD
Principal investigator's title: Clinical Director, Consultant Gynaecologist
Tel: (01) 556 7900
Data Controller's/joint Controller's Identity: Dr Louise Glover, PhD
Data Controller's/joint Controller's Contact Details: Merrion Fertility Clinic, (01) 556 7900
Data Protection Officer's Identity: Carl Alfvag
Data Protection Officer's Contact Details:dpo@nmh.ie

I confirm that I have explained the nature and purpose of this treatment to the person(s) who signed the below consent.

Signed: _____ (Staff member) Date: _____

Study title: Does PICSI lead to improved outcomes in fertility treatment?

This consent covers the use of PICSI in an ICSI cycle, as part of the above research study trial.

1. I have read and understood the Patient Information Leaflet about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.

2. I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out.

3. I understand that I can withdraw my consent up until the time of the egg collection.

4. I understand that, if there are found to be fewer than two mature eggs at the time of egg maturity assessment, the cycle is no longer eligible to be included in the study trial.

5. I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential.

6. I consent to take part in this research study having been fully informed of the risks, benefits, and alternatives.

7. I give explicit informed consent to have my data processed as part of this research study. I can withdraw my data at any time.

8. I consent for PICSI to be used for sperm selection as part for this research project. I understand that this is my own decision.

9. I consent to be re-contacted by researchers about possible future research related to the current study for which I may be eligible.

I have been given adequate information orally and in writing about this treatment and I have discussed this with Merrion Fertility Clinic staff.

Signed: _____ Signed: _____

Date: _____ Date: _____