

## PRESS RELEASE

# First baby born as a result of a new reproduction technique that activates sperm

- The system developed by Fecundis, based in the Parc Científic de Barcelona, activates the ability of sperm to fertilize by reproducing in the laboratory the process that occurs naturally in the woman reproductive tract
- The first clinical study to validate the system concluded with the birth of a child to patients with a long history of infertility and opens the doors to increased success rates in assisted-reproduction treatments
- The number of high-quality embryos obtained from treated sperm cells increased by 63% compared to usual clinical practices, which would cut the time and cost of these treatments in half
- Results show the usefulness of the technique in increasing the number of embryos available in each treatment

**Barcelona, 20 June 2023.** According to the WHO, 1 in 6 couples will face infertility in their lifetime and will need medical assistance to conceive. However, only 1 of every 3 assisted-reproduction treatments results in a birth of a child. To improve these outcomes, the focus has historically been on the female gamete, the oocyte. However, it has been discovered that the semen contributes beyond fertilization, and that its activity is key for the correct development of embryos and consequently the success of treatments.

A new assisted-reproduction technique that activates sperm has now successfully completed its first clinical trial with the birth of a baby to parents with a long history of infertility. The new technique was developed by Fecundis, a med-tech start-up based in Barcelona's Science Park, and the baby was born in Argentina after treatment at the In Vitro Buenos Aires Clinic, a partner in the research along with CONICET and the Universidad Nacional de Rosario. Another two pregnancies achieved with the same technique are currently in their third trimester.

### A technique that focuses on sperm

The sperm activation technique developed by Fecundis, called HyperSperm, reproduces in the sperm the same biochemical changes that are naturally produced in the female reproductive system during fertilization. These changes allow the sperm to acquire a movement pattern called hyperactivation, which is critical to the success of fertilization but which is not correctly reproduced with current assisted-reproduction techniques.

*"In assisted-reproduction clinics, in general, little attention is paid to sperm and we lack standardized protocols for handling semen,"* explains the international expert in reproductive medicine **Rita Vassena**, CEO of Fecundis. *"We are gaining more and more understanding of the sperm role beyond fertilization and its effects on the development of embryos and even the overall success of pregnancies. We have developed our treatment with this new focus on the male gamete in order to maximize the success of treatments for all*

patients.” Vassena emphasizes that the results of the study “are encouraging, as they would mean that the time and cost of assisted-reproduction treatments could be cut in half.”

For years, the sperm was considered a mere vessel for the father’s genetic contribution to the embryo. “We now know that the functions of the sperm go far beyond simply providing the paternal genetic material to the embryo,” explains **Dario Krapf**, an international expert in sperm biology and Head of R+D+i at Fecundis. “The molecular processes that take place after ejaculation (called capacitation) has a crucial effect on the correct development of the embryo. The technology developed by Fecundis recreates in the laboratory the natural changes that a sperm cell undergoes in the female tract, enabling a highly efficient assisted reproductive procedure.”

### **A pioneering clinical study**

To test the viability of the technique for fertility treatments, Fecundis launched a pilot trial in Argentina, where it carries out part of its activity, in 2022. 10 infertile couples with a long history of unsuccessful in vitro fertilizations (IVF) treatment were selected as they started a new treatment using donor eggs. To analyze the results of the study, each couple’s eggs were divided into two groups: half of them were fertilized according to the standard of care while the other half were fertilized after treating the semen with HyperSperm.

To assess the effectiveness of the treatment, the usual IVF success parameters were analyzed, especially with regard to fertilization and embryo development. The sperm treated with HyperSperm generated 63% more high-quality embryos compared to the control group. Some patients also received embryo transfers derived from the HyperSperm treatment that have resulted in pregnancies: one has given birth to a baby, while two others are in their third trimester.

The data obtained at the end of this study are encouraging and suggest that HyperSperm could cut the time to achieve a pregnancy through assisted reproduction by half, making the process cheaper and accessible to more patients. However, the researchers reiterated that this is a pilot study and, as such, is limited in size and scope. A definitive assessment of the clinical value of the technique in larger trials is already underway.

### **About Fecundis**

**Fecundis** is a clinical-stage med-tech company focused on developing disruptive technologies to increase the success rate of assisted reproduction. Its mission is to revolutionize reproductive medicine by focusing on the sperm in order to increase the effectiveness and reduce the economic and psychological impact of fertility treatments. The company, based in Barcelona’s Science Park, was founded in 2022 by the international expert in reproductive medicine Rita Vassena, formerly Global Scientific Director of the Eugin Group, and by scientists Mariano Buffone and Dario Krapf, leaders in sperm biology research with more than 50 years of accumulated experience in human fertility.

**More information:** <https://fecundis.com/>

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