

Patient Information

Mechanisms of stem cell development during human embryogenesis

Summary

The main goal of this research is to study how human embryos develop to understand why many human pregnancies fail. To achieve this goal, we will receive donated frozen human embryos from CARE Fertility clinics and store them in our laboratory. We will thaw the donated human embryos to use them in our experiments, we will grow them in a dish, and we will analyse them using special techniques.

We are asking if you would like to donate embryos that you no longer want to use for your treatment or that are considered unsuitable for treatment to our research project.

Background

Six days after fertilization the human embryo contains two main types of cells, those that will generate the future foetus and those that will form the structures that support pregnancy, such as the placenta. As soon as the embryo implants in the womb, these stem cells start to divide, become reorganized, and generate cells with different identities and functions. If all these events do not happen correctly, this can result in pregnancy loss. It is estimated that around 30% of human embryos fail to develop shortly after implantation, but the reasons why remain unknown. To understand the causes of failure, we need to study the genes, chromosomes, and proteins that are important for the development of the embryo

What is the purpose of this study?

We want to understand how human embryos develop and what happens when pregnancies fail. We hope that the results of this study will benefit medical knowledge in several important ways, including:

- Understanding how cells in the human embryo become specialised to take on different functions. The formation of different types of cells is fundamental for the proper development of the embryo.
- Understanding how embryos acquire their shape as they develop beyond implantation. These findings could help to explain why so many human pregnancies fail shortly after implantation.
- Finding out how alterations in the normal number of chromosomes affect embryo development. Human cells have 46 chromosomes which contain the genetic material. Alterations in this number typically lead to pregnancy loss, but the reasons behind this remain unknown.
- Developing stem cell lines that can be taken out of the embryo and multiplied in the laboratory for many years. This can help us study and understand pregnancy loss and potentially develop new drug treatments.

How will the work be carried out?

We will carry out the following laboratory procedures:

- Growing human embryos in a dish up to day 13 of development, the internationally recognised limit for the study of human embryos in the laboratory.

- Analysing the cells of the embryo using specific chemical compounds to understand the genes and proteins that they express.
- Exposing the growing embryos to specific compounds to assess how they respond.
- Recording the development of the embryos using specialised microscopes.
- Deriving stem cell lines from the embryos. If an embryo is used to produce stem cells, it is separated into individual cells so that it is no longer intact. Stem cells survive and multiply indefinitely and can be used to study many types of diseases as well as search for treatments.
- Altering the cellular composition of a human embryo by introducing human or mouse stem cells. The resulting embryo will contain cells originally coming from different embryos. This technology will allow us to understand how human embryos cope with errors.

At the end of the research, all embryos will be allowed to perish.

How will this help me?

The research we do will not help you personally, and we are unable to provide any information on any particular embryo. However, the information we get from this study may help us to improve fertility treatments, prevent pregnancy loss, and create new research tools. Information collected will be studied by scientists and published in medical and scientific journals. We will also communicate our results more broadly to the public. You will not be identified personally in any way in any publication, scientific presentation, or talk for a general audience.

It is possible that discoveries resulting from research on donated embryos, or stem cells generated from them, could result in patents or licenses being awarded to the researchers or commercial organisations. You will not receive any financial benefit from research discoveries arising from the embryos you donate or from stem cells generated from them.

Where will this work be performed?

This study will be done in collaboration with researchers at the MRC Laboratory of Molecular Biology (LMB) in Cambridge, under a research license issued by the Human Fertilisation and Embryology Authority (HFEA) and approval of the East of England – Cambridgeshire and Hertfordshire Research Ethics Committee. The funding for this research is covered by the Medical Research Council (MRC), which supports the research in the group of Dr. Marta Shahbazi, and funding from the CARE Fertility Group and its Rachel Foundation. Additional information can be found at: <https://www2.mrc-lmb.cam.ac.uk/>

Important Regulatory Aspects

- Do I have to donate my embryos?

You are under no obligation to donate embryos for research and if you decide not to, this will not affect your treatment in any way. If you do decide to donate your embryos, we will only use embryos that you no longer want to use for your treatment or that are considered unsuitable for treatment

- What happens if I want to withdraw my consent?

If you have consented to the use of your embryos in the research project you can still withdraw your consent to research at any time up to when the embryos are used in the research project.

If you choose to do this, it will not affect you or your treatment if that is still ongoing. If you wish to withdraw your consent, please email alison.campbell@carefertility.com, or contact the unit at which you were treated and ask to communicate with the Laboratory Manager.

- What happens if my embryos are used to derive stem cells?

If your embryos are used to derive stem cells, once these have been created, they may continue indefinitely and be used in many different research projects. These stem cells will be deposited in the UK Stem Cell Bank, which will allow researchers from other laboratories, nationally and internationally, to access the cells and use them for their own research. The stem cells, or any discoveries made using them, could potentially be patented and used for commercial purposes. In this case, you would not receive any financial benefits.

- How is my confidentiality preserved?

The scientists involved in the research may have access to identifiable information, which cannot be erased before providing the researchers with the 'straws' containing the frozen embryos. The identifying information will however be discarded with the straws once the embryos are used for the research and will not be used or recorded by the researchers. The embryos will be coded and your identity and participation in the research will be kept strictly anonymous. If stem cells are generated in the research, a sample of these will be deposited with the UK Stem Cell Bank. In this case, only, it will be necessary for your treatment clinic to provide a copy of your consent form in confidence to the Secretary of the UK Stem Cell Steering Committee. Your identity will not be disclosed to the staff of the UK Stem Cell Bank or anyone else.

- What should I do if I have any questions about the research?

Please note that we encourage you to ask any questions that are on your mind at the time of signing the Consent Form or anytime thereafter. Access to counselling independent from the study team is available. If you have any questions, you should contact the Laboratory Manager at the CARE clinic at which you had your treatment.