Announcement

The HOPE Registry: first US registry for oocyte cryopreservation

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Abstract

The Human Oocyte Preservation Experience (HOPE) Registry is an initiative of EMD Serono which aims to systematically track the outcomes of oocyte cryopreservation cycles and validate the efficacy and safety of techniques to freeze and thaw oocytes. Beginning in November 2008 (ASRM, San Francisco, CA), the registry will be performed as a national Phase IV observational 5-year study (including 3 years of enrolment and 2 years follow-up of babies born) in the USA and will enrol approximately 400 women of reproductive age who have thawed frozen oocytes for subsequent use through in-vitro fertilization (IVF) and embryo transfer (ET). Data relating to controlled ovarian stimulation protocols, freezing and thawing of oocytes, culture and transfer of resulting embryos, implantation rates, pregnancy outcomes and information on child health and development after birth and at 12 months will be recorded. It is anticipated that the HOPE Registry will provide answers to various unresolved questions from healthcare providers and their patients who use oocyte cryopreservation to preserve fertility, such as oocyte cryopreservation and thawing techniques and other factors associated with successful cycle outcomes

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Oocyte cryopreservation could potentially provide a valuable method of fertility preservation for women undergoing cancer treatment. A better understanding of oocyte physiology, the use of improved culture media and implementation of innovative cryopreservation techniques have increased the number of pregnancies resulting from fertilization of thawed oocytes in recent years. Although the lack of long-term safety data currently prevents the use of elective oocyte cryopreservation to defer childbearing (Practice Committee of the Society for Assisted Reproductive Technology and Practice Committee of the American Society for Reproductive Medicine, 2007), this emerging technology may help couples realize their long-term reproductive goals.

The aim of The Human Oocyte Preservation Experience (HOPE) Registry is to track the outcomes of oocyte cryopreservation cycles and validate the efficacy and safety of techniques used to freeze and thaw oocytes. It will be the first such prospective registry in the US and will be performed as a Phase IV observational study over 5 years (including 3 years of enrolment and 2 years follow-up of babies born) and listed on www.clinicaltrials.gov.

The HOPE Registry will follow a strict study protocol for patient enrolment and data collection in line with guidelines of the United States Agency for Healthcare Research and Quality. Formal enrolment on a national basis will begin during the meeting of the American Society of Reproductive Medicine (ASRM, San Francisco, CA, November 2008). The registry will enrol approximately 400 women of reproductive age who have thawed frozen oocytes for subsequent use through in-vitro fertilization (IVF) and embryo transfer (ET). All patients will be required to give written informed consent before enrolment in the registry. Local ethics committee or Institutional Review Board approval will be required for each participating centre, and the registry will be conducted according to the principles of good clinical practice and the Declaration of Helsinki. As this is a purely observational study, patient management will be decided by the caregiver and patient rather than according to a pre-defined ovarian stimulation protocol.

The registry will be open to all qualified investigators interested in recording data relating to the frozen/thawed oocytes and the culture and transfer of resulting embryos. Data on controlled ovarian stimulation protocols, oocyte freezing and thawing procedures, embryo culture methods and transfer procedures, implantation rates, and pregnancy outcomes will be collected. Information on child health and development after birth and at 12 months of age will also be collected. Genetic screening data (such as preimplantation genetic diagnosis, amniocentesis, chorionic villous sampling, cord blood cells) will be used to compare the genetic makeup of babies from cryopreserved oocytes with those from other established assisted reproductive techniques. Registry outcomes will be published annually to inform patients and caregivers about the efficacy of the different cryopreservation techniques and post-natal outcomes.

The HOPE Registry is expected to provide a real-world view of oocyte cryopreservation and, alongside this, answers to various unresolved questions from healthcare providers and their patients who use this innovative technique to preserve fertility, such as oocyte cryopreservation and thawing techniques and

other factors associated with successful cycle outcomes. In the future, cryopreservation may become a tool for preservation of female gametes, facilitating the formation of oocyte cryobanks for donation, and thereby bringing real hope to women who would otherwise have no childbearing options.

References

Practice Committee of the Society for Assisted Reproductive Technology, Practice Committee of the American Society for Reproductive Medicine 2007 Essential elements of informed consent for elective oocyte cryopreservation: a Practice Committee opinion. *Fertility and Sterility* **88**, 1495–1496.

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