

## Pregnant women support first maternal gene therapy trial

**Pregnant women would be willing to trial maternal growth factor gene therapy to treat severe early-onset fetal growth restriction (FGR) in their unborn babies, according to a new study. If the proposed trial goes ahead it is likely to be the first time maternal gene therapy has ever been used.**

The study which examined ethical and legal questions raised by maternal gene therapy was carried out by University College London (UCL), Queen Mary University of London (QMUL), and 8 other leading EU higher education institutions and industrial partners who form the EVERREST\* consortium.

The consortium have been working together since 2013 to develop a therapy for FGR, a condition which affects up to 8 per cent of all pregnancies. Inadequate uterine blood flow, termed placental insufficiency, is the underlying abnormality in many cases. There is currently no treatment.

Dr Anna David (UCL Institute for Women's Health) and the EVERREST consortium lead said:

"The EVERREST consortium aims to carry out the first trial of this therapy in pregnant women whose babies are most severely affected by fetal growth restriction to test out its safety and efficacy. We hope that the therapy will reduce stillbirths and neonatal deaths, and improve neonatal and long term outcomes for affected babies. As this is potentially the first clinical use of gene therapy during pregnancy we were keen to establish responses to important ethical questions raised by the proposed trial."

Once fetal growth restriction is identified in mid pregnancy, parents currently face a stark choice between delivering their baby very prematurely in the knowledge they might die in the neonatal intensive care unit, or allowing the pregnancy to continue with the strong likelihood that the baby will die in the womb. Babies born from growth restricted pregnancies are not only at increased risk of perinatal death and complications such as cerebral palsy, but there are long term consequences for their health including diabetes and cardiovascular disease.

The EVERREST Clinical Trial would involve administration, via interventional radiology, of a Vascular Endothelial Growth Factor (VEGF) gene therapy into the mother's uterine arteries in pregnancies affected by severe early onset fetal growth restriction in mid-

pregnancy. In previous preclinical studies performed by EVERREST partners, the VEGF gene medicine has been found to increase the maternal blood flow to the womb and placenta, which safely increased fetal growth and birthweight in growth restricted pregnancies. The EVERREST team now wish to test the therapy in the clinic.

Professor Richard Ashcroft, Professor of Bioethics, QMUL said:

"Our study concluded that there were no ethical or legal objections to a trial of maternal gene therapy in pregnancy. Women who had experienced pregnancies affected by fetal growth restriction were generally interested in participating in clinical trials which might potentially benefit their unborn child. The findings of our study are a major boost for the team's work on developing a treatment for fetal growth restriction which could save thousands of lives."

The study involved interviews with key stakeholder groups and patients in Europe including midwifery and medical organisations, parental support groups, disability rights groups and women whose previous pregnancies had been affected by early onset fetal growth restriction. Of the 55 stakeholder groups contacted, 34 participated in the study. 21 women whose pregnancies had previously been affected by early onset fetal growth restriction were also interviewed. The researchers evaluated the ethical and social acceptability of a proposed clinical trial using maternal growth factor gene therapy.

Dr David added: "Almost all women viewed the proposed trial positively, and most felt that they would have wanted to participate. The views expressed by the women in our study echo the findings of other qualitative studies exploring women's experiences of obstetric research. We must strive to develop therapies for pregnancy diseases such as fetal growth restriction, where no treatments currently exist."

The research was funded by the European Commission and supported by researchers at the National Institute for Health Research (NIHR) University College London Hospitals Biomedical Research Centre. The EVERREST trial is due to commence in early 2017, subject to ethical and regulatory approval, at University College London Hospital before being rolled out to University Medical

Centre Hamburg-Eppendorf in Germany, Hospital Clinic of Barcelona in Spain, and Lund University in Sweden.

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**Notes to Editors****Article:**

Ethics and social acceptability of a proposed clinical trial using maternal gene therapy to treat severe early-onset fetal growth restriction

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**Follow link for the full article:**

<http://onlinelibrary.wiley.com/doi/10.1002/uog.15880/full>

\*Higher education institutions and industrial partners who form the EVERREST consortium:

University College London

University College London Hospitals NHS Foundation Trust

FinVector Vision Therapies Ltd,

Magnus Life Science Ltd

Euram

University of East Finland

Queen Mary University of London

Lund University

University Medical Center Hamburg-Eppendorf

Hospital Clinic Barcelona and IDIBAPS

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**About ISUOG:**

1,400 women die from pregnancy related causes every day, worldwide. The International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) is dedicated to ensuring that all women have access to competent ultrasound and that obstetric and gynecological conditions are effectively diagnosed. ISUOG delivers high quality learning through its education program and World Congress and disseminates research information and clinical guidance through its journal *Ultrasound in Obstetrics & Gynecology*. With more than 13,500 members across 128 countries, ISUOG is committed to improving health outcomes for women and their families across the world.

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