

Ethics and ethical evaluation of a proposed clinical trial with maternal uterine artery vascular endothelial growth factor gene therapy to treat severe early onset fetal growth restriction in pregnant women

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Medical care in pregnancy raises many ethical questions about the inter-relationship between the woman and the fetus. These questions are heightened when trying to develop a gene therapy which would be administered to pregnant women for a fetal complication. As part of the EVERREST Project these issues have been explored through a literature review and interviews with medical, parental, and disability group stakeholders across the EU.



Baby Riggall was born with severe FGR at 28 weeks weighing 640g (average baby weight 3.5kg)

Introduction

Fetal growth restriction (FGR) affects 7% of pregnancies and is a major cause of stillbirth and neonatal mortality and morbidity [1]. The EVERREST project aims to carry out a phase I/IIa safety / efficacy study in 4 EU countries, of Vascular Endothelial Growth Factor (VEGF) gene therapy given into the mother's uterine arteries as a potential treatment for severe early onset FGR. In pregnant sheep, uterine artery delivery of VEGF gene therapy relaxes the vessel, induces vessel contraction and generates new per-arteriolar blood vessels [2,3]. In a sheep model of FGR, treatment reduces the number of offspring classified as 'markedly growth restricted' and mitigates 'brain-sparing' [4].

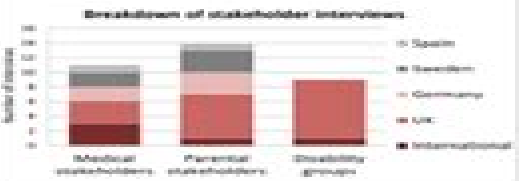
The possibility of administering a gene therapy to a pregnant woman in order to treat a fetal complication raises several important ethical questions.



Newborn lambs from a clinical trial of VEGF gene therapy

Methods

The literature relating to the ethics of research in pregnant women, including gene therapy in pregnancy, was explored through database searches in English (Medline and Google Scholar), the national languages of Consortium partners (Spanish, Catalan, Finnish, Swedish, German), and French. Relevant documents from the European Union, Council of Europe, World Medical Association, UNESCO, and other jurisdictions including the USA, were also reviewed. Interviews were carried out with 34 stakeholders identified through internet searches and with the input of Consortium clinical partners in Spain, Sweden, UK and Germany. The interviews were based on a semi-structured questionnaire, lasting 30-60 minutes, and were conducted by native language speakers, with the exception of interviews in Sweden, which were conducted in English.



Conclusion

Neither the literature review nor the stakeholder interviews identified any fundamental ethical or legal objection to the proposed intervention. Interviews are currently on-going to explore the attitudes of women, and their partners, who have had a previous pregnancy affected by severe early onset FGR.

Results

There was concern that women may feel obliged to undergo gene therapy, compromising their autonomy.

Who is the patient?
A key question in the ethical literature relating to research in pregnancy is whether there is one patient, the pregnant woman, or two patients, the pregnant woman and the fetus. In most EU member states the fetus has no legal status, but the moral status of the fetus, and how this relates to the personhood of the pregnant woman, is greatly debated. Stakeholder interviews reflected this range of attitudes.

Maternal treatment for fetal benefit
The literature suggests that, with either the one patient or two patient models, such treatment is permissible but not obligatory. If the pregnant woman is the only patient, it is still within her rights as an autonomous decision-maker to undergo treatment for the benefit of the fetus. Similarly, if both the pregnant woman and the fetus are patients then such treatment should be permissible, after careful consideration of the balance of risks and benefits. Medical stakeholders stressed that this is the situation for many procedures in current clinical practice, and stakeholders mentioned indirect benefits for the woman.

Challenges of decision-making
Stakeholders were concerned about the psychological stress women would face at the time of decision-making, given that they would already be coping with a diagnosis of severe early onset FGR.

"It's a huge decision to make and if you decide 'yes, I will go through with this' and then maybe something went wrong, the mother will always feel that they made a bad mistake"

Parental organisation, Sweden

"I think the mother will do almost anything for her child and will accept anything ... and this constitutes of course a certain problem"

Medical stakeholder, Germany

Challenges for informed consent
The regulatory literature highlights the importance of informed consent, free from coercion. Respondents spoke of the need for independent advice for trial participants, for example by psychologists, midwives, and parental organisations. Informed consent would need to be a continuing process rather than a single event.

"I think the most important thing in this trial as with all trials is that one explains it at the level of the patient and not at an academic level but at the level of the patient ... one needs to use simple vocabulary and one needs to keep on repeating it because these parents ... are in a certain state of shock"

International parental organisation

Effect on disabled people
Most respondents, including disability groups, felt the aim of the trial was to avoid termination and stillbirth rather than eliminate disability, so did not consider it discriminatory.

Acceptability of gene therapy
Overall, the novelty of gene therapy was not a concern for respondents. The exception were stakeholders from Germany, where there is a negative societal view of gene therapy.



EVERREST consortium kick-off meeting, UCL, January 2013

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