



Patient Interviews - A Lay Summary



EVERREST

An important component of EVERREST Project is the ethical, legal, regulatory and social evaluation of the acceptability of vascular endothelial growth factor gene therapy in severe early-onset fetal growth restriction (FGR). FGR is a serious condition and has a significant risk of stillbirth. Affected babies are small and may be born very early, which can cause them problems as a baby and later on in life. Until the trial is carried out it is not known whether this growth factor therapy will work for FGR and improve growth and whether it is safe in humans.

The project has already conducted a review of the bioethics literature in this area and has ascertained the views of key stakeholders, as reported previously. Interviews with women/couples who have experienced pregnancy affected by severe FGR were a further important component of this work. The interviews were conducted with women/couples in the UK, Sweden, Germany and Spain and focused on ten main topics covering potential ethical and societal objections to the proposed EVERREST therapy and clinical trial.

The overall conclusion drawn from these interviews was that women who have experienced pregnancy affected by severe FGR had a generally favourable view of the ethical and social acceptability of EVERREST.

Other key findings were as follows:

- When asked at what point they viewed their unborn child as a separate person, most pregnant women reported that they took this view from early on in pregnancy and would generally do anything to help this child.
- While decision-making in a pregnancy affected by severe early-onset FGR was difficult, women did not feel incapable of arriving at a decision regarding any treatment options but would listen to the advice of healthcare professionals and discuss the options with their partners.
- Women were generally interested in participating in clinical trials particularly where the trial conferred a potential benefit to the unborn child.
- Concerns regarding informed consent for trial participation were thought to be the same as in any other trials in pregnancy affecting the fetus. All those interviewed were clear that accurate and adequate information would have to be given in order for women to make a decision on participation in the trial.
- Overall, the proposed EVERREST trial was viewed in positive terms and the women interviewed did not consider the issue of possible disability of their child due to prematurity as a reason not to participate. However, women would generally not want to expose themselves to serious risks.
- Neither the issue of the treatment being a form of gene therapy nor the administration of the therapy seemed to cause any major concern.