The EVERREST team supports wider inclusion of pregnant women in clinical trials research

It is well recognised by national and international bodies that women, and particularly pregnant women, have too often been excluded from clinical research, resulting in a lack of evidence-based treatments. The conclusions of the EVERREST bioethics study, reported here, that women and their partners welcome the chance to be offered a potential treatment for severe early onset fetal growth restriction, support the research progress that is being made to develop obstetric therapeutics. During a clinical trial of a new drug, patients who receive the drug are carefully monitored for any untoward medical occurrence. These “adverse events” are graded for their severity to allow comparison between trials. We have identified the need for an internationally recognised set of definitions and grading criteria for pregnancy-related adverse events in obstetric clinical trials of therapeutics.

To address this need, EVERREST Co-ordinator, Dr Anna David (Reader in Obstetrics and Fetal Medicine at UCL), and Dr Rebecca Spencer (Clinical Research Fellow, Fetal Medicine, UCL) have convened a working group to develop definitions and criteria of adverse events, based on national and international guidelines. The group includes specialists in obstetrics, fetal medicine and neonatology, as well as representatives of the pharmaceutical industry from across Europe and the US.

The group met for the first time in Barcelona in May 2015 and, after intense discussion, agreed on a set of criteria for comprehensive sets of fetal and obstetric adverse events. Adverse events in neonates will be addressed at a future meeting. Draft versions of these criteria will be circulated for review by a wider group of experts, and the EVERREST team’s long term aim is to have them adopted by regulatory agencies.

EVERREST team members involved are Dr Eduard Gratacos, Dr Francesc Figueras, Dr Fatima Crispi, and Dr Albert Batista (Barcelona), Dr Anke Diemert (Hamburg), and Professor Karel Marsal (Lund). External participants include obstetrics and fetal medicine specialists Professor Steve Thornton (University of Exeter UK), Professor Magnus Westgren (Karolinska Institutet, Sweden), Jan Deprest (University Hospitals Leuven, Belgium) and Christoph Lees (Imperial College London, UK); perinatal cardiologist Professor Helena Gardiner (University of Texas Medical School, US), paediatric surgeon Professor Alan Flake (University of Pennsylvania, US), and maternal health specialists from the pharma-ceutical industry: Kathleen Beech and Marcy Powell (GlaxoSmithKline, North Carolina).