Clinical trial reports improved health and survival outcomes for babies born from high-risk pregnancies

A clinical trial that strives to determine the optimal method to schedule delivery times for women affected by fetal growth restriction reports better than expected health and survival outcomes in these new born babies, due to improved antenatal management protocols.

Early results from a large Europe-wide clinical trial, to be presented today (Sunday) at the ISUOG World Congress in Sydney report an increase in short-term survival (up to 92%) and a reduction in severe mortality (30% of live births) compared with studies of a similar target, but with smaller cohorts of patients.

'TRUFFLE' is the largest clinical trial to date looking into outcomes in pregnancies complicated by severe, early-onset, fetal growth restriction.

Fetal growth restriction is a condition in which the fetus does not grow adequately in the womb, due to a lack of nourishment and oxygen. There are a variety of risk factors that cause fetal growth restriction, which affects 3-5% of all pregnancies; of these 40% are considered high-risk pregnancies.

Doctors are faced with a serious dilemma when deciding on optimal delivery times for these pregnancies; delivering too early exposes new borns to health risks associated with premature birth and delivering too late could cause more harm and even mortality to fetuses growing in environments with very low oxygen and nutrition levels.

The TRUFFLE study aims to optimise the protocols for determining when women with high risk pregnancies should deliver, testing three different fetal monitoring policies.

The clinical trial recruited women from 20 centres across Europe, which all adhered to the same antenatal management protocol. In total, 503 women, 32 weeks pregnant or less, whose babies were affected by fetal growth restriction were included in the study and randomised onto one of the three fetal monitoring policies.

In one group of patients delivery time was determined by monitoring the fetus' heart rate. In the other two groups, timing was based on changes in the Doppler ultrasound reading, which measures the rate of blood flow in the baby's blood vessels.

The study aims to monitor which of the three practices provides the best health outcome in these high-risk pregnancies by comparing the neurological age of babies at age 2 years.

Preliminary results of the trial, which were published early online in the leading journal *Ultrasound in Obstetrics & Gynecology* on 24 September 2013, reveal a positive impact of a standardised antenatal management protocol, not previously noted in similar studies. As such, the study reports a total of 395 babies surviving without severe morbidity.

Co-author Dr Christoph Lees of Imperial College Healthcare NHS Trust comments, "Although the effects of the different fetal monitoring practices on long-term neurodevelopment are not yet known, these management protocols would help effect a reduction in perinatal mortality and short-term morbidity in pregnancies complicated by severe, early-onset fetal growth restriction."

This TRUFFLE study was born out of an ISUOG focus group set up to provide guidance on the role of Doppler ultrasound in obstetrics and continues to drive improvements in clinical management.

ENDS

For more information, contact us at:
E: **msims@isuog.org**
T: **+44 (0)20 74719955**
Or visit our website: **isuog.org**

Notes to Editors

Relevant sessions at the ISUOG World Congress:

IUGR detection and management:
Clinical lessons from the TRUFFLE study (C. Bilardo)
Sunday, October 6, 2013, 17:20- 17:40
Bayside Auditorium A, Sydney Convention and Exhibition Centre.

Full article:

Perinatal morbidity and mortality in early-onset fetal growth restriction: cohort outcomes of the trial of randomized umbilical and fetal flow in Europe (TRUFFLE)
C. Lees, N. Marlow, B. Arabin, C. M. Bilardo, C. Brezinka, J. B. Derks, J. Duvekot, T. Frusca, A. Diemert, E. Ferrazzi, W. Ganzevoort, K. Hecher, P. Martinelli, E. Ostermayer, A. T. Papageorghiou, D. Schlembach, K. T. M. Schneider, B. Thilaganathan, T. Todros, A. van Wassenaer-Leemhuis, A. Valcamonico, G. H. A. Visser and H. Wolf, the TRUFFLE Group
Volume 42, Issue 4, Date: October 2013, pages 400-408

About the ISUOG World Congress
The ISUOG World Congress is the leading event in women's imaging and a forum for the dissemination of the highest quality research and clinical information in the field of ultrasound in obstetrics and gynecology. The Congress brings together international expertise to promote clinical excellence and encourage research collaborations to improve health outcomes for women affected by pregnancy and gynecological complications, across the world. The 23rd annual ISUOG World Congress is taking place from 6-9 October, 2013 at the Sydney Convention and Exhibition Centre incorporating the 43rd Annual Scientific Meeting of the Australasian Society of Ultrasound Medicine.

isuog.org/WorldCongress/2013/Press

****PRESS CALL****
Press are invited to the World Congress Plenary day on **Sunday 6 October** for an official press call with international experts from **13.45** in Bayside 105, Sydney Convention and Exhibition Centre, followed by a complimentary lunch. For full details and access to press releases, please contact Matilda Sims at **msims@isuog.org** or on **+ 61 (0) 455 845 024**

About ISUOG
1400 women die from pregnancy related causes every day, worldwide. The International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) is a membership organisation dedicated to ensuring access for health professionals to the highest quality education, training and research information so that ultimately, all women have access to competent ultrasound and that obstetric and gynecological conditions can be effectively diagnosed. ISUOG delivers high quality learning through its education program and disseminates research information and clinical guidance through its journal Ultrasound in Obstetrics and Gynecology and World Congress. With more than 7000 members across 126 countries, ISUOG is committed to improving health outcomes for women and their families across the world.