18th World Congress in Fetal Medicine

IMPACT Barcelona: Improving Mothers for a better PrenAtal Care Trial. A RCT to reduce fetal growth restriction

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Objective

Fetal growth restriction (FGR) is an important cause of perinatal mortality and morbidity and with long-term consequences. Recent research findings point at suboptimal maternal diet and maternal stress as potentially important contributors. As there is no current therapy for this condition, an important goal is to prevent it.

Methods

The main purpose of this randomized controlled trial (RCT) is to reduce the prevalence of FGR in a population of pregnant women at higher risk for this condition, with two strategies based on maternal lifestyle intervention: (1) improved nutrition based on Mediterranean diet and (2) stress reduction based on Mindfulness techniques.

Results

The current study is a RCT following a 1: 1: 1 ratio, parallel, open blind from a single center. All eligible women attending second trimester scan (19-23 weeks) are evaluated according to the criteria of the Royal College of Obstetricians and Gynecologists for the risk to have a restricted fetus. Those found to be at high risk will be invited to participate in the RCT. Participants are randomized to three different arms: (1) nutrition intervention on Mediterranean diet (MD) based on individual visit of 30 minutes assess every month, monthly group classes of 1 hour and supplements of extra-virgin olive oil (2 liters/month) and walnuts (450 g/month), (2) Mindfulness Based Stress Reduction (MBSR) program which consists in 8 weeks of 2.5 hours of group classes of a 20-22 people, one full day and daily home practice (3) usual care without any intervention. Several life-style questionnaires, nutritional interview, and biomarkers are taken at the beginning and at the end of the interventions in all participants. Further scans are conducted for the assessment of fetal growth, fetal cardiac function and neurodevelopment. Pregnancy and neonatal outcomes will be collected and analysed. Follow-up of the offspring will be extended until 24 months of corrected age. The study sample size (n=1218, 406 per arm) was designed to guarantee an 80% statistical power for the principal endpoints. Primary outcome is to reduce the prevalence of FGR, defined as birthweight <10th centile, by 30% (attend improvement: reduction from 30% to 20%). Secondary outcomes are the reduction of 50% of adverse perinatal outcome, defined as the presence of any of the following perinatal measures: preterm birth, preeclampsia, perinatal mortality, severe FGR (birthweight <3rd centile), metabolic acidosis, major neonatal morbidity.

Conclusion

The analysis will be performed according to the intention-to-treat principle. The study is registered on Clinical Trials Gov, trial registration number: NCT03166332.