WOMEN'S HEALTH RESEARCH ROUNDUP

Issue 1 — February 2015

Building On Success

Welcome to this New Year's first Research Newsletter. Last year proved exceptionally successful on the research front with a number of notable achievements. GSTT has become the national coordinating centre for the NIHR comprehensive research network. This coincided with GSTT leading the league tables for the busiest trust for participant recruitment to CRN non commercial trials. In addition women's services remain the busiest specialty within the trust and early metrics suggest this trend has continued and extended into 2015. King's College London have been highly rated in the REF (a research assessment exercise for universities bases on their outputs over the last few years). Indeed for the category including women's we were ranked top in the country. All this success has provided an excellent platform to continue our work, but we shouldn't forget that this achievement is based on many individuals contributing throughout all the clinical areas, with a supportive ethos to research. A plethora of new trials are about to start, thanks to a number of grants being awarded and all this work will ultimately improve the care of all the women we look after. All of us involved in coordinating the research are very grateful for these efforts and we look forward to working with you all in the coming year. Professor Andrew Shennan

Research Midwives mostly work Monday to Friday 9-5 we can be contacted via email **ResearchMidwives@gstt.nhs.uk**. If you would like to contact us about any queries, questions or you think a woman is eligible for a research study then send us an email and one of us will reply. Alternatively you can call us on extension: **83634** or **84559.**

PETRA: Threatened Preterm Labour

This study aims at improving care of women with symptoms of threatened preterm labour (TPTL). Most women with TPTL are not in "true" labour, but many are admitted to hospital and treated unnecessarily, "just in case". This is very costly for both the women and the NHS. This study will recruit women with TPTL symptoms, mainly through the Antenatal Day Assessment Unit and Hospital Birth Centre. Risk factors, fetal fibronectin and transvaginal cervical length measurements will be used to develop and validate an easy-to-use risk assessment tool. This tool will generate an individual risk score (percentage risk of delivery with clinically important time frames, such as 48 hours and 2 weeks), which could aid assessment and lead to more appropriate care. Some of the women will also be asked to take part in a qualitative study exploring women's experience of TPTL risk assessment, management and factors that affect decision making. For more information please contact Jenny Carter on ext: 83641

MAVRIC: RCT of 3 Types of Cervical Cerclage

MAVRIC TRIAL

Recruitment has finished for MAVRIC: a multicentre RCT of transabdominal versus transvaginal cervical cerclage.
Women with a previous failed vaginal cerclage are managed variably in their next pregnancy. Transabdominal cerclage might be more effective, but is much more invasive as it requires a general anaesthetic and a caesarean birth.
133 women have been recruited and we are waiting for the last to be delivered. We will then analyse the results and publish our findings.

PAIRS (Pregnancy Adaptations In Renal disease Study)

PAIRS is a prospective cohort study of women with chronic kidney disease (CKD) in pregnancy. Eligible women include those with known or suspected CKD (creatinine>85 in pregnancy or PCR>30 before 16/40). The study also wants to recruit women without CKD. Participants will have a blood and urine test taken once in each trimester. This will be coordinated with routine tests whenever possible. For further information contact Dr Kate Wiles or midwives Jenie Fetherston and Ruth Cate on ext: 83634

DAPPA: Diagnostic Accuracy in Pre-Eclampsia using Proteinuria Assessment

This UK-wide study is investigating which urine test best predicts the development of severe pre-eclampsia. 24hr urine is compared against spot PCR and spot ACR, as well as comparing different ways of analysing in the lab. The study also investigates the cost effectiveness of these different methods. This study is based in Newcastle, and St Thomas' is a recruiting site.

Women ≥ 20 weeks' gestation, with hypertension and a trace or more of proteinuria are eligible. Women with renal disease, pre-pregnancy diabetes, or chronic hypertension are excluded.

Please let us know if you see a woman who might be eligible (before you take bloods, preferably). If you are caring for a DAPPA lady, please take an MSU and pop it in the fridge in the dirty utility by theatres (remember to label with name, date and time, and mention DAPPA). For more information please contact Ruth Cate on ext: 83634

DAPPA

UPBEAT, UPBEAT TEMPO & UPBEAT TEMPO HEART

UK Pregnancies: Better Eating and Activity Trial is a RCT to improve outcomes for obese pregnant women, with particular reference to reducing the risk of developing GDM. UPBEAT has now finished recruiting, having recruited 1556 women, making it the largest study of obese pregnant women in the world!! Initial findings will be published very soon! Our last Upbeat baby will be 6 months old in summer 2015. We have also commenced UPBEAT Tempo, the follow on study to UPBEAT, and are seeing the recruited women and their children at age 3 years. In addition UPBEAT participants and lean controls are being asked to take part in UPBEAT TEMPO HEART looking at cardiovascular function in the children of obese and non obese women. For more information on all of these studies please contact Hayley Tarft on ext: 83634

OBS2 (Obstetric Bleeding Study 2)

OBS2 Obstetric Bleeding Study 2

Obs2 is a multicentre, prospective, double blind randomised control trial that will be coming soon. This study investigates the effects of fibrinogen conscentrate vs placebo, whether replacing fibrinogen early during PPN, using a fibrinogen concentrate, reduces the number of women needing a blood transfusion.

Due to delays in lab tests fibrinogen, participants will have fibtern assays checked using a Rotern machine. Fibrinogen concerntrate or placebo will be given according to these results. For further information please contact Zeenath Uddin ext: 83634

PEACHES: Pre-Eclampsia And Chronic Hypertension, rEnal and SLE

This study investigates different proteins in the urine (the urinary proteome) and biomarkers in the blood of women with suspected pre-eclampsia, those diagnosed with pre-eclampsia, women with renal disease, lupus, or chronic hypertension. The study aims to aid in diagnosing pre-eclampsia and even predict its onset. Non-pregnant women with chronic hypertension, lupus, or renal disease have also taken part.

Women are asked to provide urine and blood samples. Outcomes data is obtained from clinical notes. Please let us know if you see a woman with suspected pre-eclampsia, renal disease, lupus or chronic hypertension. Please tell us before you take any bloods as we will need to take research bloods and are happy to take clinical bloods at the same time. For further information please contact Ruth Cate on ext: 83634

PEACHES

FACT: Folic Acid Clinical Trial

Folic Acid Clinical Trial – Effects of folic acid supplementation in pregnancy on pre-ecamplsia

This randomised, double blinded study evaluates a new pre-eclampsia prevention strategy of high dose folic acid supplementation from early pregnancy until delivery. Eligible women are randomised between 8^{+0} - 16^{+6}/40 to either 4.0mg folic acid or placebo tablets daily. Eligible women will have either: a documented history of previous pre-eclampsia, twin pregnancy, pre-existing hypertension or BMI ≥ 35kg/m^2. For further information or for any referrals please contact Jenie Fetherston or Ruth Cate on ext: 83641

PANDA: Pregnancy And Chronic hypertension

Pregnancy And Chronic hypertension: Nifedipine or labetalol as Anti-hypertensive treatment.

This feasibility study aims to determine the optimal treatment for chronic hypertension in pregnant women. Eligible women are randomised to either Nifedipine or Labetalol between 12^{+0}/40 to 27^{+6}/40 weeks pregnancy. Any woman who has chronic hypertension (defined as diastolic blood pressure >=90mmHg) at booking or before 20 weeks' gestation, or had required treatment outside pregnancy and/or at time of referral is eligible. Please contact the Panda Team (Dr Louise Webster, Jenie Fetherston and Ruth Cate) on 07530513875 or email the research midwives with referrals.

PHOENIX

Phoenix started recruitment at the end of September. The research addresses whether delivery in women with pre-eclampsia between 34+0 and 36+6 weeks reduces maternal complications without short and long term detriment to the infant, compared to the routine expectant management and delivery at 37 weeks. Following consent women are randomly allocated to either; planned immediate delivery with IOL commencing within 48 hours or expectant management and delivery at 37 weeks (NICE guidelines). Following birth, women will be asked to complete questionnaires at 6 months and 2 years to follow up their child's development. Inclusion criteria is women's PET (ISSHP defined), who have a viable singleton or DCDA pregnancy, the only exclusion criteria are inability or unwillingness to give informed consent or clinical decision to deliver within 48 hours. For more information contact Laura Scholtz on 07541226835 or ext: 83634

OC Research Study

Large observational study that focuses on the genetics and metabolomics of obstetric cholestasis. Samples are collected at one time point or longitudinally (if possible) from women with OC and also from controls, their babies and other relatives.

The aim of this study is to increase understanding of the OC And therefore improve management and pregnancy outcomes. For further information please contact Hayley Tarft on ext: 83634

Research Midwife Champion Forum Meeting

In December the first national Research Midwife Champion Forum meeting was held in Manchester.

The meeting was attended by national representatives from all CRN's and chaired by Professor Andrew Shennan, Speciality Lead for Reproductive Health and Childbirth. Annette Briley is the London (South) representative.

The vision of the Forum is to create an integrated research delivery workforce that can efficiently support recruitment into reproductive health and childbirth studies.

During this inaugural meeting the aims of the group were established:

- To develop a community of Reproductive Health and Childbirth delivery staff
- To provide a forum for sharing experiences, good practice and challenges
- To provide a forum to discuss recruitment challenges and generate solutions for Reproductive Health and Childbirth Portfolio studies
- To identify training needs for the workforce and explore opportunities for delivery of relevant training
- To ensure a "joined up" approach to delivery of Reproductive Health and Childbirth studies across the whole workforce
- To create a platform to demonstrate good practice both within the Speciality and to a wider audience.

For more information please contact Annette Briley on 020 7188 3643

or email: annette.briley@kcl.ac.uk

This newsletter provides information about some of the clinical trials currently taking place in Women's. There are many more!

We are a very successful research area and thank everyone for their contribution to this success.