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Update from NRS Reproductive Health and Childbirth Specialty Group October 2019

Good News Stories in Reproductive Health and Childbirth Research

At the European Federation of Colposcopy (EFC) Congress held in Rome, 25-28 Sept 2019, **Professor Maggie Cruickshank**, NHS Grampian R&D Director, was elected as President-elect taking up Presidency in 2022. EFC aims to promote the best standards of colposcopy in Europe and has 36 member national societies and 5 associate member countries. Going forward, EFC looks to achieve its ambitions by training and standard setting but also collaborating in colposcopy and cervical cancer screening research across Europe.

Dr Sarah Martins da Silva, NHS Tayside, has been named on the '100 Women 2019' BBC's list of inspiring and influential women from around the world. Sarah is a clinical academic and runs a Translational research programme focused around sperm biology, fertilisation events and drug discovery for male infertility.

Many Congratulations to Maggie and Sarah!

The Next Deadline for submitting Good News for the CSO is 25th October 2019.
Please send your Good News to abha.maheshwari@abdn.ac.uk or maria.amezaga@nhs.net

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The following Trials are looking for Centres.
Please let Abha/ Txaro know if you wish to participate
abha.maheshwari@abdn.ac.uk or maria.amezaga@nhs.net

ALIFE 2. Anticoagulants for Living FoEtuses in women with recurrent miscarriage and inherited thrombophilia. CI: Professor Siobhan Quenby. Sponsor: UHCW NHS Trust

Alife 2

Trial Synopsis

Trial Summary:

ALIFE 2 is a multi-centre randomised open-label, phase III clinical trial to compare LMWH with standard pregnancy surveillance in women with inherited thrombophilia and a history of recurrent miscarriage.

Eligible patients will be registered onto the trial. As soon as pregnancy is confirmed (<7 weeks gestations) participants will be randomised to one of two groups:

- **Arm 1:** standard pregnancy surveillance plus LMWH once daily, starting immediately after randomisation. LMWH will be discontinued at the beginning of labour/end of pregnancy.
- **Arm 2:** standard pregnancy surveillance.

All participants will be encouraged to take folic acid as routine prophylaxis for neural-tube defects.

For the purposes of the ALIFE2 trial recurrent miscarriage will be defined as 2 or more consecutive or non-consecutive miscarriages.

STOP-OHSS (Shaping and Trialling Outpatient Protocols for Ovarian Hyper-Stimulation Syndrome): A feasibility study and randomised controlled trial, with internal pilot, to assess the clinical and cost-effectiveness of earlier active management of OHSS. CI: Mr Mostafa Metwally. Sponsor: Sheffield Teaching Hospitals NHS Foundation Trust

Research question

What earlier active outpatient management interventions for women with moderate to severe, early or late ovarian hyperstimulation syndrome (OHSS) are acceptable and feasible, and what is the clinical and cost-effectiveness of such interventions compared to conventional conservative management?

Aims and objectives

Our main research questions are:

1. Can we develop acceptable and feasible protocols for earlier active management in two distinct populations (early and late moderate to severe OHSS) for testing in two concurrent RCTs?
2. What is the clinical and cost effectiveness of the developed early active management interventions compared to conventional conservative management of women with early moderate to severe OHSS?
3. What is the clinical efficacy and cost effectiveness signals of the developed early active management intervention compared to conventional conservative management of women with late moderate to severe OHSS?

New Study. Reminder!

The WILL Trial. When to Induce Labour to Limit risk in pregnancy hypertension -a multicentre, randomised controlled trial. *The pilot phase is underway and they are looking at approaching sites for the main phase.* Let us know if you are interested and will send you the Protocol Summary. Please complete the feasibility survey at this link: https://www.smartsurvey.co.uk/s/FeasibilitySurvey_v1point12_20190108/

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Specialty National Lead Letter to Trusts

UCON study (Ulipristal acetate versus conventional management of heavy menstrual bleeding: a randomised controlled trial)

UKCRN portfolio ID 18534

Date: 8th October 2019

Re: UCON Phase III Trial. Support research and tomorrow's treatment

Dear UCON PI,

As you know, the infrastructure provided by the NIHR's Clinical Research Network (CRN) is based on the NHS England foundation that research is vital in order to transform services and improve outcomes. The journey from research to practice may vary in timeframes and challenges, but by addressing the most important research questions with robust clinical trials, we will keep moving forward.

UCON is one such trial which is investigating the use of ulipristal acetate for the management of heavy menstrual bleeding. The sample size is 302 and the UCON **trial requires just 79 more patients to achieve the primary objective**, to determine if ulipristal acetate (UPA, Esmya) is more effective at reducing the burden of heavy menstrual bleeding (HMB) symptoms than the levonorgestrel-releasing intra-uterine system (LNG-IUS, Mirena or equivalent) after 12 months of treatment. As you may be aware, there was a Europe-wide UPA drug alert for a few months in 2018. However, the European Medicines Agency (EMA) Medicines and Healthcare products Regulatory Agency **(MHRA)** then **approved the drug for use** and the EMA has also requested that **research is still needed.**

UCON is the only independent trial investigating the use of UPA for heavy menstrual bleeding. Anecdotes from patients who previously participated in the trial indicate they have seen an improvement in their quality of life, and no safety issues have emerged. Patient representatives, the trial steering committee, data monitoring and ethics committee, the RCOG gynaecology clinical studies group and CRN clinical leads around the country support the trial. Indeed, the clinical leads suggest the **UCON** trial, led by Professor Hilary Critchley (CI), **is in a unique position to inform the NICE guidelines** and tomorrow's treatment.

Ulipristal acetate is already widely used by Trusts and recommended by NICE for the treatment of heavy menstrual bleeding in women with fibroids three centimeters or more in diameter. In the UCON trial, women with no or small fibroids and HMB, who are randomised to the treatment arm will take UPA in three courses over a 12 month timeframe (each course is 12 weeks, four weeks off treatment in between each course). Participants will be randomised individually in an equal ratio to either UPA or LNG-IUS.

We have copied in your local CRN Research Delivery Manager to support you. We ask that you reply by 31-Oct-2019 to indicate whether you can support UCON by recruiting women within your clinic.

With kind regards

Yours sincerely,

Mr Nigel Simpson
NIHR-CRN National Specialty Lead Reproductive Health & Childbirth
Senior Lecturer and Honorary Consultant in Obstetrics & Gynaecology, University of Leeds
n.a.b.simpson@leeds.ac.uk

Professor Hilary Critchley
UCON CI; Professor of Reproductive Medicine, MRC Centre for Reproductive Health, University of Edinburgh
hilary.critchley@ed.ac.uk