

## Please help us in a national randomised trial to prevent iron deficiency in pregnancy

Our NIHR funded pragmatic national trial will compare the effects of ferrous sulphate iron supplementation vs placebo, in non-anaemic pregnant women, on pregnancy outcomes including preterm birth, stillbirth, neonatal death or a small for gestational age birth.

The PANDA (Primary prevention of maternal ANaemia to avoid preterm Delivery and other Adverse outcomes) programme of research addresses anaemia in pregnancy which affects around 30% of women and is primarily caused by iron deficiency. We know there is an association between iron deficiency anaemia and adverse outcomes including maternal mortality, haemorrhage, preterm birth, stillbirth, and infant neurocognitive development in the early years of life, but we don't know how best to prevent the anaemia.

Our new, definitive trial; called PANDA - Prevention of Anaemia builds on our previous successful dose identification trial which also developed a behavioural intervention designed to improve adherence to treatment. Feedback from focus groups and interviews with healthcare professionals is incorporated throughout our research.

Participants: We aim to recruit 11,020 non-anaemic pregnant women from participating maternity units over 18 months. We estimate that around 90% of women attending the units for their first visit will be eligible.

## Inclusion criteria:

Healthy non-anaemic pregnant women receiving NHS maternity services, identified at booking or dating ultrasound scan

## **Exclusion criteria:**

Women with haemoglobinopathies, a current diagnosis of anaemia of any cause, severe gastrointestinal disease, or multiple pregnancy.

Consent Procedure: We will use multiple options including e-consent to minimise the burden on site staff and maximise participant recruitment.

Intervention: Ferrous Sulphate 200mg tablets, dose regimen to be confirmed following analysis of our dose finding study

**Comparator:** Placebo matched to Ferrous Sulphate tablets

## **Co-Chief Investigators:**

**Professor Simon Stanworth** 

**Professor Marian Knight** 

University of Oxford and NHS Blood and Transplant

National Perinatal Epidemiology Unit (NPEU)

**Co-Investigators:** 

**Professor David Churchill** Consultant Obstetrician

**Professor Chris Gale Consultant Neonatologist** 

Professor Andrew Farmer **Professor of General Practice** 

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The Development and Analysis of the Behavioural Intervention

Ms Joanne Murray Service-user Co-Investigators

**Dr Oliver Rivero-Arias Health Economics** 

Dr Noemi Roy Iron Supplementation Expertise

Sponsorship, trial management, and statistical analysis provided by NHSBT Clinical Trials Unit

If you would like your site to be part of this trial or would like further information, please contact the trial management team at: PANDA@nhsbt.nhs.uk



