





Primary prevention of maternal Anaemia to avoid preterm delivery and other adverse outcomes (PANDA Programme NIHR200869)

Investigating the prevention of anaemia to improve pregnancy outcomes

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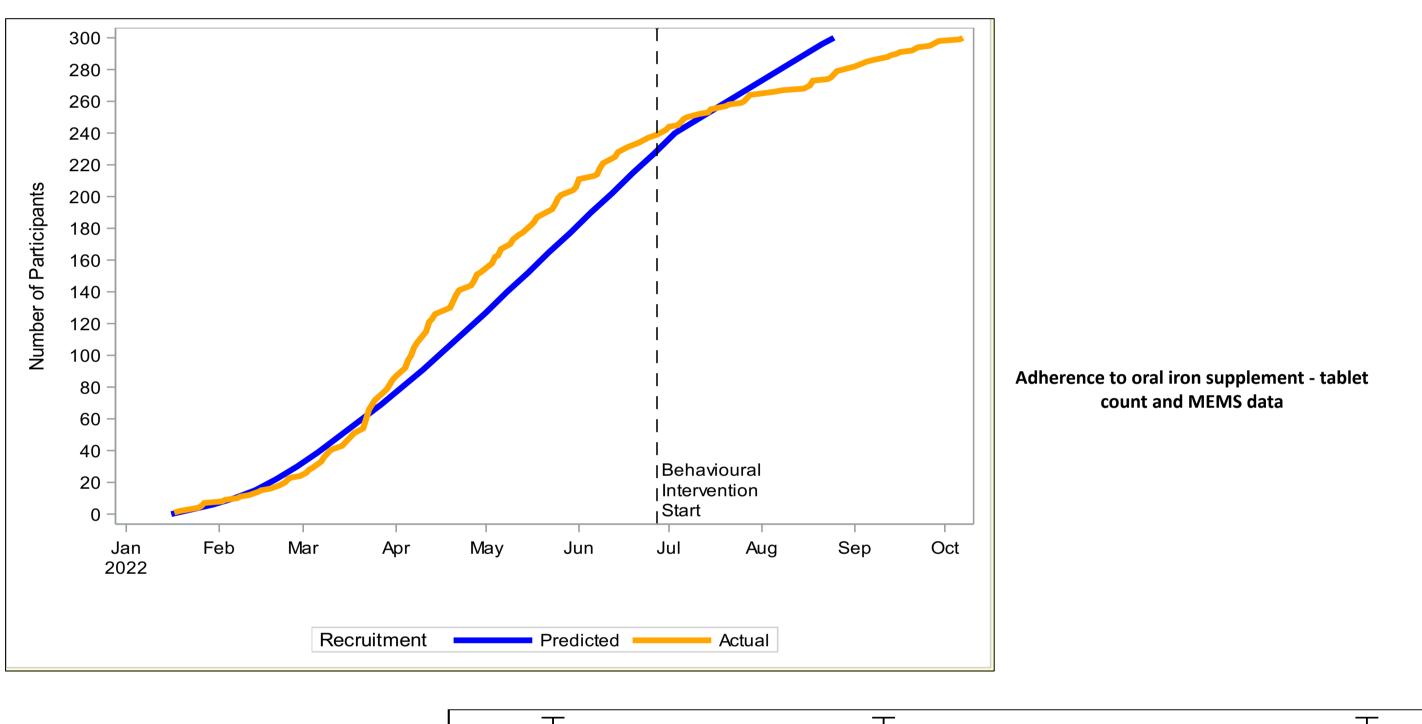
Background

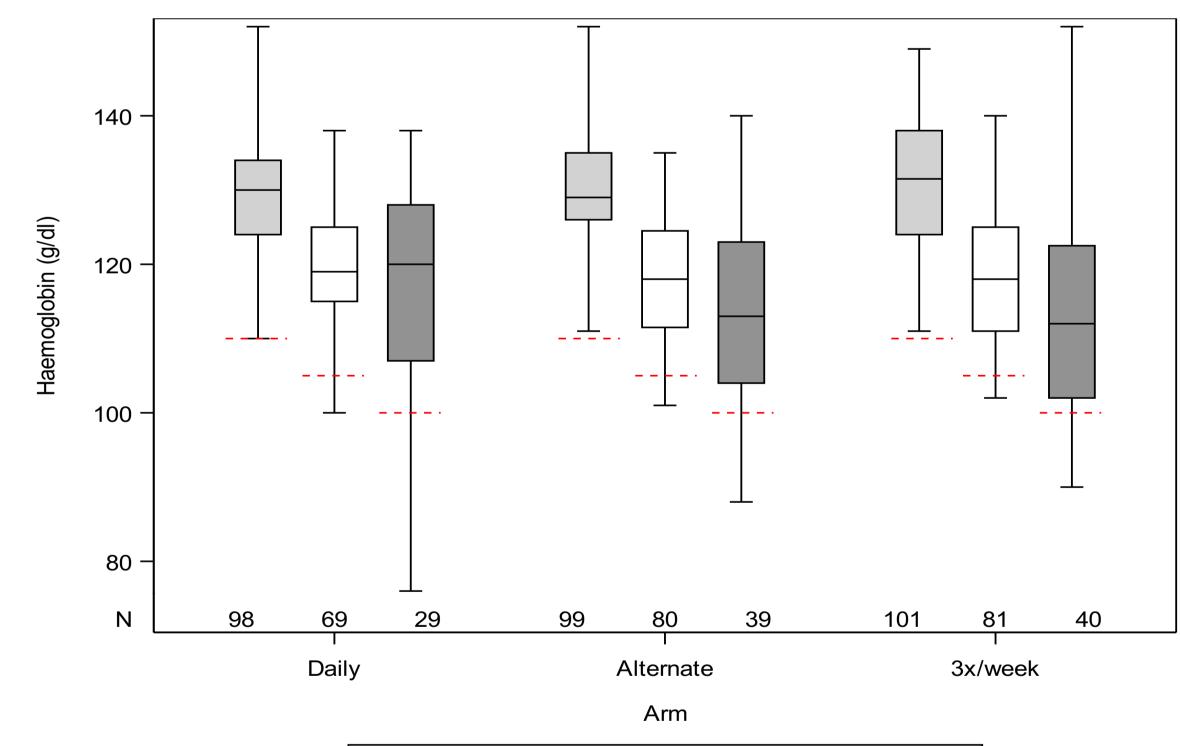
Among its many associations with adverse obstetric outcomes, iron deficiency anaemia (IDA) is associated with dysfunctional labour and atonic postpartum haemorrhage. Credible mechanisms including cellular hypoxia have been put forward as the cause.

Other associated adverse outcomes are preterm birth, small for gestational age, postnatal depression, stillbirth and neonatal death. It also causes women to experience malaise, fatigue, poor exercise tolerance and impaired cognition. Treatment of IDA is known to be associated with high rates of non-response for many reasons. Uncertainty remains on the clinical impact of oral iron supplementation to prevent anaemia during pregnancy.

The PANDA programme of 5 workstreams is designed to address the problem of prevention.

To choose the optimal dose for a large double-blind placebo-controlled trial we conducted an RCT comparing daily, with alternate day, with 3 times a week. Some results are shown below. There were no differences in adherence, symptoms/side effects and maintenance of haemoglobin between the 3 arms and the daily dose of 200mg ferrous sulphate was chosen to take forward to the main trial.





Objectives and Methods Main RCT

Aim: To evaluate the clinical- and cost-effectiveness of a primary prevention strategy for iron deficiency anaemia in pregnancy with an optimised low dose oral iron supplementation intervention.

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.

☐ Randomisation ☐ 28 weeks ☐ Delivery

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

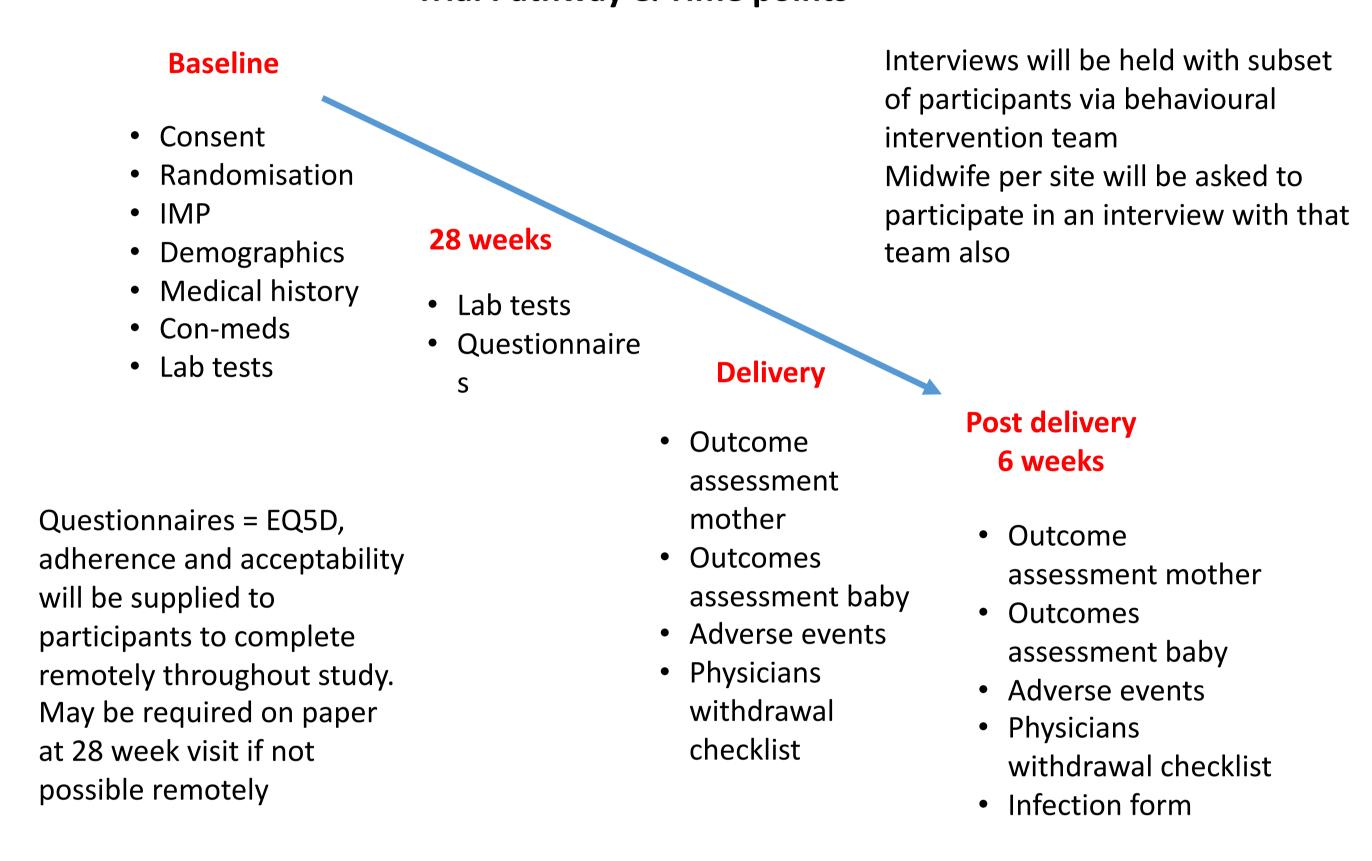
Intervention: Ferrous Sulphate 200mg tablets, dose regimen to be confirmed following analysis of our dose finding study

Comparator: Placebo matched to Ferrous Sulphate tablets

The outcome measures have been chosen to comprehensively answer the questions about the prevention of anaemia in pregnancy and relevant to PPI

- Clinical outcomes:
 - Primary Preterm birth, small for gestational age, mortality
 - Secondary inc; prevention of anaemia, haemorrhage, infection, mental health, maternal quality of life & infant development
- Health Economics:
 - Quality of life, Use of resources inpatient and outpatient
- Adherence:
 - Adherence questionnaire at 28 weeks
 - Fidelity survey 28 weeks

Trial Pathway & Time points



References



PANDA Trial team

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Co-Chief Investigators: Professor Simon Stanworth University of Oxford and NHS Blood and Transplant. Professor Marian Knight National Perinatal Epidemiology Unit (NPEU)

Co-Investigators:

multi-centre study

Professor David Churchill Consultant Obstetrician, Professor Chris Gale Consultant Neonatologist, Professor Andrew Farmer Professor of General Practice, Professor Helen Spiby Professor of Midwifery.

Dr Fabiana Lorencatto Dr Elise Crayton The Development and Analysis of the Behavioural Intervention, Dr Stephanie Lax Ms Joanne Murray Service-user Co-Investigators

Dr Oliver Rivero-Arias Health Economics, Dr Noemi Roy Iron Supplementation. Expertise

More information & expressions of interest

For more details and to express and interest in the trial visit the PANDA website: PANDA@nhsbt.nhs.net