INFORMATION BROCHURE for clinicians: IRONWOMAN study

What is this:
This leaflet is to give you some information about the IRONWOMAN study. This study aims to treat pregnant women in mid pregnancy with iron deficiency anaemia. The study is being conducted by Dr Antonia Shand, Dr Amanda Henry, Dr Luke Grzeskowiak, Dr Giselle Kidson Gerber and A/Prof Natasha Nassar of the Royal Hospital for Women, University of New South Wales, University of Adelaide and The University of Sydney. The study is being paid for by the National Blood Authority.

The primary aim:
is to determine the health related quality of life in women given intravenous (IV) iron and placebo oral tablets, compared to oral iron tablets or placebo saline infusion. Secondary aims include assessing feasibility and acceptability of blinding/use of placebo intravenous iron infusions to patients and clinicians, treatment side-effects and adherence, and haematological measures in women receiving IV versus oral iron in a blinded, randomised fashion.

Study type:
Two-arm placebo-controlled randomized trial, with blinding of patients, clinicians and outcome assessors.

Inclusion criteria:
Pregnant adult women >=18 years of age with singleton or twin pregnancy.
Mild-moderate iron-deficiency anaemia (IDA) of pregnancy (Haemoglobin 80-104 g/L and Ferritin <30µg/L)
Between 26 and 32+6 weeks' gestation

Exclusion criteria
Age<18 years, higher-order multiple pregnancy, Haemoglobin <80g/L, anaemia without iron deficiency, known malabsorptive syndromes affecting the uptake of oral iron, contraindication/known hypersensitivity to either oral iron or intravenous iron, already received intravenous iron during this pregnancy, or taking ≥80mg/day of elemental iron for the last 2 weeks, active severe mental health condition or intellectual disability precluding informed consent, women with active bleeding, women who are likely to give birth in the next 6 weeks, blood transfusion this pregnancy, history of anaemia due to another cause e.g. thalassemia, hypersplenism or haemolytic anaemia. Major medical illness such as cardiac disease.

Setting
Royal Hospital for Women and St George Hospital, Sydney

Interventions
Women and clinicians will be blinded to study medications.
Women will be randomised to receive:
1. Intravenous ferric carboxymaltose (FCM) 1000mg on a single occasion following treatment allocation, and daily placebo tablets from treatment allocation to birth OR
2. Elemental oral iron capsules 100mg daily plus 350mcg folic acid from treatment allocation to birth and a placebo intravenous saline infusion on a single occasion.

Routine Antenatal Care
Women will continue to be seen as per their usual antenatal care schedule with midwife and/or doctors. A leaflet will be attached to the woman's yellow card (handheld record) about the IRONWOMAN Study, and documentation of study participation will occur in eMaternity and the paper antenatal file. Clinicians will be asked not to undertake additional iron studies or FBC until the 4 week visit, or give additional iron during that time.

Study Visit at 4 Weeks
At 4 weeks after IV treatment women will be seen for assessment of health related quality of life (HRQoL), repeat blood test (FBC, iron studies), questionnaire regarding which treatment the patient believes she was allocated, questions regarding treatment side effects, and adherence check. Clinicians will be provided with a copy of the full blood count results at that time. Clinicians will be blinded to the iron study results, but these can be obtained from the research midwife if required.The clinician will continue to manage the iron deficiency anaemia, once they have the results. The research team will contact the clinical team by telephone if the haemoglobin remains <105g/L, 4 weeks after treatment.

Other assessments
Women will be sent an email at 8 weeks post-infusion and again 6 weeks after the birth.
Women will not be charged for their study medication. They may withdraw at any time.
We will also be recruiting healthy controls who will be part of a substudy at the Royal. These women will not receive treatment.

Birth Admission
Maternal FBC and iron studies will be sent at birth.
Cord blood for Haemoglobin and ferritin will be sent after birth.

THANK YOU FOR YOUR CONSIDERATION
Please contact the investigators if you have any questions about the study on Antonia.shand@sydney.edu.au or Amanda.henry@unsw.edu.au.
The research midwives can be contacted by phone on 0434 567 732 or by email at Jennifer.goth@health.nsw.gov.au
This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Reference number 2019/ETH10550.