INFORMATION for GPs about the IRONWOMAN study

We are starting the IRONWOMAN study at the Royal Hospital for Women in May 2021. This is a study for the treatment for iron deficiency anaemia in pregnancy. The study is being undertaken at the Royal Hospital for Women and St George Hospital.

Inclusion criteria:
We are including women with a **Haemoglobin of 80-104 g/L** and **Ferritin <30µg/L.**
Women must be ≥18 years, a singleton or twin pregnancy and **26- 32+6 weeks'** gestation.

Exclusion criteria: Women must not already have received intravenous iron in pregnancy, or have been treated with more than 80mg oral iron for two weeks.

Study design:
This is a double blinded randomized controlled trial- so women and clinicians will be blinded to the treatments women receive. All women will receive tablets and an infusion. All women will be treated for their iron deficiency anaemia.

Women will be randomised to receive either:

- Intravenous ferric carboxymaltose (Ferrinject) 1000mg on a single occasion and daily placebo tablets until birth
  OR
- Elemental oral iron capsules 100mg daily plus 350mcg folic acid until birth and a placebo intravenous saline infusion on a single occasion.

We aim 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.

Routine Antenatal Care
Women will continue to be seen as per their usual antenatal care schedule. A leaflet will be attached to the woman's yellow card (handheld record) about the study. All study medications are free.

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) and questionnaires. Clinicians will be provided with a copy of the full blood count results at that time. The clinician will continue to manage the iron deficiency anaemia. The research team will contact the clinical team by telephone if the haemoglobin remains <105g/L, 4 weeks after treatment.

If you have any patients who may be eligible and or interested, please contact the research midwife on 0429 557 084 or 0407 498 197 (Monday-Friday 9-5).
Please contact the investigators if you have any questions about the study on Antonia.shand@sydney.edu.au.

THANK YOU FOR YOUR CONSIDERATION.

7 June 2021