Project title: Screening and Induction of Labour: OUTcomes for mothers and babies - The SAIL-OUT Pilot RCT

Background and rationale

Induction of labour is a process where a woman's labour is brought on using medical methods. These methods include vaginal medication (prostaglandins), insertion of a balloon catheter into the cervix, rupturing the obstetric membranes (breaking the 'waters') and/or an intravenous infusion of oxytocin.

Planning to induce labour near term (before 40 weeks' gestational age) has been shown to reduce the risk of caesarean section compared with planning not to induce the labour and has been shown to improve outcomes for babies [1-7].

However, routinely offering induction of labour to pregnant women close to their due date remains controversial despite evidence of clinical benefits for mothers and babies.

Project aims or objectives

We are currently conducting a pilot randomised controlled trial of induction of labour for preventing caesarean section. As many women do not want to have their labour induced, we have developed a screening tool – a clinical risk prediction calculator based on a logistic regression analysis. The tool predicts women at high risk of caesarean section for slow progress in labour. It involves collecting maternal demographic data and performing an ultrasound examination at 36 weeks' gestational age. About 20% of women have a positive screening test and are eligible for randomisation.

It is expected that the screening process will result in most women avoiding an induction of labour.

The pilot study has ethics approval and has commenced. We have recruited 7 women so far and the planned sample size is 60. Recruitment temporarily ceased due to COVID-19 restrictions.

Research design and proposed methodology

***Population*:** Women who are pregnant with a single baby and who have a positive screening test for high risk of caesarean section for slow progress in labour

***Intervention*:** Planned induction of labour at 39 weeks' gestational age

***Comparator*:** Planning not to induce labour at 39 weeks' gestational age (induction can occur later due to medical indications or other reasons)

***Outcomes*:** caesarean section for slow progress in labour; caesarean section for any indication

Study conduct:

- Consent for screening will occur at $36^{(+0)}$ to $38^{(+0)}$ weeks' gestational age when the women presents for her routine 36 weeks ultrasound
- A screening algorithm applied to estimate the risk of CS for slow progress in labour.

- Women will be informed if they were at “Low risk” (< 20%) or “High risk” (≥ 20%) of CS for slow progress in labour.
- Women at “Low risk” will not be randomised.
- Women at “High risk” will be randomised to planned IOL or expectant management.
- Women will be followed up after birth, and at 6 weeks, 6 months, and 12 months.

Timeline and proposed workload

Ideally the student should be able to commence working on the study in February/March 2021.

It is expected the workload is about 2 days/week for 6 months, or about ~400 hours.

Description of skills student is required to have

We anticipate that the student will assist in recruitment (but will have substantial support in this process)

The student will draft a manuscript in the format of report on a randomised controlled trial for a journal article

If the student makes a substantive contribution, it is expected they will be a co-author on the publication. The student will not necessarily be the first author.

This project would suit a student who have studied introductory biostatistics and experience with using statistical software such as SAS or SPSS is desirable. (i.e. completed PHCM9498)

The project involves recruiting women to the trial and good communication skills are important.