In partnership with:

The SWITCh Trial (Sterile Water Injection Techniques Comparison Trial)

A randomised, controlled trial of a single versus a four intradermal sterile water injection technique for relief of continuous lower back pain during labour.

Health professional information sheet

As a midwife or medical officer involved in the care of women in labour we would like you to be familiar with the SWITCh trial and its aims, including the recruitment, consent, randomisation and data collection process.

This information sheet aims to provide you with some important information regarding the SWITCh trial. Further details can be obtained from the clinical investigators via the above contact details.

Background

Almost one in three women suffers continuous lower back pain during labour and birth1. Sterile water injections (SWI) of the lower back have been used in midwifery practice at Mater Mothers’ Hospital birth suites since February 2009 to provide pain relief to women experiencing lower back pain during labour. The most frequently used SWI technique consists of four intradermal injections of sterile water into the skin surrounding the Michaelis rhomboid over the sacral area. High quality evidence from systematic reviews supports the four injection SWI technique as an effective intervention for the management of continuous back pain during labour2,3. However, the authors also highlighted one trial4 that reported a comparable reduction in pain scores following administration of a singular SWI technique at the most painful point. This trial, however, was not adequately designed to compare SWI techniques. A single injection SWI technique would offer clinical improvements including less discomfort and greater acceptance of the procedure by women during labour. Use of a single injection technique would also reduce the number of staff and time required to administer the procedure with relative cost benefits.

Aim of the study

The aim of this study is to determine whether a single intradermal SWI technique provides similar pain relief for women with lower back pain in labour compared to the four injection intradermal technique.

Primary outcome: Relief of pain measured by VAS at 30 minutes post-intervention.

Secondary outcomes:

a) Pain relief measured by VAS 10, 60, 90 and 120 minutes post-intervention.

b) Level of administration discomfort associated with SWI procedure (measured by VAS at 10 minutes post SWI).

c) Likelihood to use again with subsequent labour.

d) Patient satisfaction with analgesic effect.
Entry criteria
- Women at term (between 37 and 42 weeks)
  - nulliparous or multiparous
  - singleton pregnancy
  - cephalic presentation
  - first stage labour (spontaneous or induced)
  - no previous analgesia
  - back pain assessed by VAS as equal to or greater than seven to qualify.

Exclusion criteria
- gestation less than 37 weeks
- multiple gestation
- malpresentation (breech transverse etc.)
- second stage labour
- pharmacological analgesia prior to SWI
- back pain assessed by VAS as less than seven
- any complications of pregnancy or labour (bleeding, diabetes, hypertension).

Sample size
A sample size of 319 will be required to achieve 90 per cent power to detect that the single injection technique is “no worse” than the four injection technique.

Recruitment and consent
A number of strategies will be used to ensure that the majority of women presenting in labour will have been provided with information regarding the trial. The majority of women will be consented to the trial in the birth suites. Consent should be attended to by either the researchers based within the birth suites, the clinical facilitators or the midwifery team leader. Consent forms and patient information sheets will be kept in the “SWI trial” folder in the birth suites and PAOU.

Treatment allocation
Consenting women will be randomised using prepared sealed envelopes containing:
- a) treatment allocation form
- b) intrapartum data collection sheet
- c) postnatal data collection sheet.

Following consent, the woman is randomised to either SWI technique. The procedure should be performed by two midwives whilst the midwife caring for the woman is absent from the room. It is important that the woman’s midwife is not aware of which technique has been used to prevent any bias during recording the VAS pain scores.

Women may have any other form of analgesia they request following the SWI procedure and may withdraw from the trial at any time.

Participating in the trial
The SWITCH trial has the potential to make a significant contribution to the evidence surrounding the use of sterile water injections and we would encourage all staff to participate in recruitment and data collection for the trial.

References