

Induction of labour at 39 weeks or beyond in multiparous women with a favourable cervix

Submission date 27/01/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 08/02/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/09/2019	Condition category Pregnancy and Childbirth	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Women in the late stages of pregnancy often want a quick delivery and sometimes wish to be induced (the use of medication to begin the process of labour) rather than waiting for labour to naturally occur. Women who have given birth vaginally before usually respond better to being induced as they have less complications and a lower rate of needing a caesarean section (the use of surgery to deliver a baby). By planning an induction date, deliveries can happen during normal work hours, which is both safer and more convenient for both the mother and the health care workers. The aim of this study is to compare birth outcomes and satisfaction with labour of women who are induced as compared to women who have standard labour (waiting for birth to occur naturally at 40-41 weeks).

Who can participate?

Adult women who are at least 38 weeks pregnant who have had a previous vaginal birth.

What does the study involve?

Participants who consent to participate are randomly allocated to having labour either induced or to having standard expectant care. Women allocated to having labour induced have a scheduled induction date once they reach 39 weeks of pregnancy. This involves being given an oxytocin (medication to induce birth) drip to begin the birthing process and then receiving standard care throughout the labour process. Women allocated to the standard expectant care have normal care with outpatient follow up, which involves waiting for birth to occur on its own. If they have not given birth by 41 weeks they are induced (according to the standard level of care). Participants are followed from recruitment until hospital discharge in order to determine their satisfaction with their birth experience and health outcomes of their babies.

What are the possible benefits and risks of participating?

There are no direct benefits to participant however participants may benefit from a faster delivery. Participants who are induced may experience less satisfactory care and poorer birth outcomes compared to participants who received standard care.

Where is the study run from?

University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
September 2016 to May 2019

Who is funding the study?
University of Malaya (Malaysia)

Who is the main contact?
Dr Aida Othman

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
UMMC MECID No. 2016927-4284 ; NMRR-17-31-33921

Study information

Scientific Title
Induction of labour at 39 weeks or beyond in multiparous women with a favourable cervix: A randomised controlled trial

Study objectives
The induction of labour at 39 weeks gestation in multiparous women with favourable cervixes compared to standard (expectant) care will result in higher patient satisfaction and permit a larger proportion of delivery during normal working hours (9am to 5pm on weekdays).

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Malaya Medical Centre Medical Research and Ethics Committee, 8/01/2017, ref: 2016927-4284

Primary study design

Interventional

Study design

Single-centre randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Healthy pregnancy at or after 39 weeks gestation

Interventions

Participants undergo an internal (vaginal) digital examination to assess the favourability of their cervix. Women with an unfavourable cervix (e.g. cervical opening less than 2 cm dilated) are ineligible for the trial and their usual care continues.

Eligible women, after providing written consent to participate, are randomised to one of two groups (labour induced or the control group) through opening the numbered sealed envelope containing their allocation. The randomisation sequence is generated using a computerised random number generator.

Group one (labour induced): Women assigned to induction of labour are given a date for their labour induction as soon as practicable upon reaching 39 weeks (if recruited at 39 weeks, as soon as possible). The appointment for labour induction is scheduled for at 8 am on a weekday. As the cervix is favourable, labour induction is expected to be initiated by breaking the water followed by a drip (oxytocin) to start contractions off. Management of labour induction is according to standard practice.

Group two (control): Women allocated to standard expectant care have normal care with outpatient follow up. This involves waiting for spontaneous labour and usually with recommendation to induce labour at 41 weeks if they still have not delivered, provided there are no interim issues identified. Management of labour induction is according to standard practice.

Participants are followed until their hospital discharge, and their babies are followed until their hospital discharge.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Delivery time (week day 9 am to 5 pm or other) is assessed from hospital records after hospital discharge
2. Maternal satisfaction of care is measured using a visual numerical rating score sheet and self-scored from 0-10, assessed after delivery

Key secondary outcome(s)

Maternal outcomes:

1. Mode of delivery is assessed from hospital records at hospital discharge
2. Oxytocin use in labour is assessed from hospital records at hospital discharge
3. Epidural use in labour is assessed from hospital records at hospital discharge

4. Number of antenatal clinic visits is assessed from hospital records at hospital discharge
5. Number of non-birth related hospital admissions after recruitment is assessed from hospital records at hospital discharge
6. Presentation at hospital admission for birth (i.e. spontaneous labour, induction of labour, prelabour rupture of membranes, planned caesarean section, and others) is assessed from hospital records at beginning of hospital stay
7. Blood loss is estimated using healthcare provider's standard estimation at delivery
8. Fever is measured using a single temperature reading ≥ 38 degrees Celsius is extracted from hospital records measured during labour, after delivery and at hospital discharge
9. Duration of hospital stay for birth admission is assessed from hospital records at hospital discharge

Neonatal Outcomes:

1. Neonatal outcomes are measured by Apgar score at 5 minutes after birth
2. Neonatal admission to special care nursery or intensive care is assessed from hospital records at infant's hospital discharge
3. Birth weight is assessed from hospital records at hospital discharge
4. Umbilical cord arterial blood pH and base excess is assessed from hospital records at hospital discharge

Completion date

03/05/2019

Eligibility

Key inclusion criteria

1. Aged over 18 years
2. At least one previous vaginal birth (birth after gestational age of 28 weeks and birth weight of over 1kg)
3. Gestational age of 38 weeks to 40 weeks at enrollment
4. Favourable cervix (Bishop Score ≥ 6 and likely to be suitable for amniotomy)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Previous caesarean section
2. Previous uterine surgery or uterine injury

3. Indication or anticipation (maternal or fetal) for early or urgent delivery
4. Contraindication for vaginal delivery

Date of first enrolment

14/02/2017

Date of final enrolment

02/05/2019

Locations

Countries of recruitment

Malaysia

Study participating centre

University Malaya Medical Centre

Jalan University

Lembah Pantai

Kuala Lumpur

Malaysia

50603

Sponsor information

Organisation

University Malaya Medical Centre

ROR

<https://ror.org/00vkrxq08>

Funder(s)

Funder type

Not defined

Funder Name

Universiti Malaya

Alternative Name(s)

University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available.

IPD sharing plan summary

Not expected to be made available