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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

Registration date
08/02/2017

Overall study status
Completed

Last Edited
02/09/2019

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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
Dr Aida Othman

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
30/09/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
160

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

Sponsor details
Jalan University
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor type
Hospital/treatment 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, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

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