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A trial of the induction of labour at 39 weeks or beyond in women who have never given birth before and have a short cervical length on ultrasound scan

Submission date
30/09/2021

Recruitment status
No longer recruiting

Registration date
06/10/2021

Overall study status
Completed

Last Edited
17/01/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Electively inducing labour at 39 weeks on a planned date as opposed to 41 weeks gestation would be better in terms of patient satisfaction; the mother has control over her delivery date instead of having to anxiously wait for the labour to happen. This would give her more freedom to choose the delivery date and reduce the anxiety of waiting for the symptoms and signs of labour. We propose that patient satisfaction would be better in patients who have planned induction of labour.

Who can participate?
Women who are aged 18 years and above between 38 - 39+6 days gestation at enrolment with no previous deliveries and no medical problems needing early induction of labour.

What does the study involve?
All eligible women will be counselled, and if agreeable, they will consent to a transvaginal scan to assess the cervical length. The cervical length will be measured three times, and the shortest cervical length will be taken. A cervical length less than 27 mm will be considered a short cervix. Women with a “sonographic short cervix” will then be randomized into scheduled labour induction as soon as practicable on the day of the following week or standard expectant management.
Women allocated to labour induction will be instructed to attend at approximately 0800 hours on the planned day. Where possible, induction is by standard obstetric management after performing a bishop score.
Women who are randomized into the expectant arm will be managed as per standard antenatal care protocol to be induced at 41 weeks unless interim issues.
Maternal satisfaction scores will be assessed after delivery using the visual numerical rating scale and scored from 0-10.

What are the possible benefits and risks of participating?
Benefits: The patient can have a planned early induction of labour. Studies show that induction of labour at 39 weeks gestation with a favourable cervix could probably reduce caesarean section and reduce the stillbirth rate. By performing vaginal scans, we identified the subgroup of patients who were easily inducible
Risks: A vaginal scan was performed on the patients included in the study. Studies have shown that it is less painful than a digital vaginal examination. Patients may have a subjective feeling of more pain when compared to normal labour when labour is being induced. Patients who undergo induction of labour may perceive pain more than the expectant management group

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?
From June 2017 to June 2022

Who is funding the study?
BKP Khas. University of Malaya research grant funding (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2017523-5254

Study information

Scientific Title
Induction of labour at 39 weeks or beyond in nulliparous women with a sonographically favourable cervix: a randomised control trial

Acronym
ISOFC

Study objectives
We hypothesise that planned induction of labour from 39 weeks gestation in nulliparas with favourable cervixes compared to expectant management will result in higher patient satisfaction and no increase in the rate of caesarean section and probable benefits to the fetus in terms of reduction in still birth and neonatal morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/08/2017, Medical Research Ethics Committee University Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +603 7949 3209/2251; ummc-mrec@ummc.edu.my), ref: 2017523-5254

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Induction of labour at 39 weeks gestation

Interventions
Cervical length will be measured three times, and the shortest cervical length will be taken. Cervical length < 27 mm will be considered a short cervix. Women with a “sonographic short cervix” will then be randomised into scheduled labour induction as soon as practicable on the following weekday (or on reaching 39 weeks and beyond if assessed prior to 39 weeks) or standard expectant management. They will be randomly allocated into either arm by opening the lowest-numbered remaining sealed envelope containing the random allocation. Randomisation sequence will be generated in random blocks of 4 or 8 using a random number generator by an investigator not involved in recruitment or direct patient care.
Women who are randomised into the intervention arm will be arranged for admission on the day of choice - no earlier than 39 week 0 days gestation. They will be instructed to attend at approximately 0800 hours on the planned day. Where possible, induction is by standard

obstetric management after performing a bishop score.
Women who are randomized into the expectant arm will be managed as per standard antenatal care protocol to be induced at 41 weeks unless interim issues.
Maternal satisfaction scores will be assessed after delivery using the visual numerical rating scale and scored from 0-10.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Maternal satisfaction measured using a numerical rating scale after delivery
2. Delivery duration measured using measured using patient records at a single time point

Key secondary outcome(s))
1. Mode of delivery measured using patient records at a single time point
2. Admission to the neonatal intensive care unit (yes/no) measured using patient records at a single time point

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Gestational age of 38 weeks to 39 weeks 6 days at enrolment
3. No other intervention currently required or anticipated
4. No medical contraindication to induction of labour.
5. Sonographically favourable cervix (cervical length less than 27 mm by vaginal scan)
6. Nulliparous
7. Singleton with live fetus
8. Cephalic presentation
9. Written informed consent
10. Willingness to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Women with a known lethal fetal congenital abnormality
2. Previous uterine surgery or uterine injury
3. Indication for early or urgent delivery
4. Contraindication for vaginal delivery
5. Medical complications during pregnancy
6. Women who book late for antenatal care and have no dating scan performed before 22 weeks to provide an accurate expected delivery date

Date of first enrolment
01/05/2017

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lot 28, Jalan Professor Diraja Ungku Aziz
Lembah Pantai
Wilayah Persekutuan
Kuala lumpur
Malaysia
59100

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

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 and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	23/05/2017	05/10/2021	No	Yes