ISRCTN10921283 https://doi.org/10.1186/ISRCTN10921283

Does providing information about induction of labour at 39 weeks earlier in pregnancy affect women's decision?

Submission date
24/08/2026

Recruitment status
Not yet recruiting

Registration date
26/08/2026

Overall study status
Ongoing

Last Edited
26/08/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Elective induction of labour at 39 weeks is one option for women with uncomplicated pregnancies. Some women choose induction, while others prefer to wait for labour to begin naturally. This study aims to find out whether providing balanced, evidence-based information about induction earlier in pregnancy influences women's decision regarding elective induction at 39 weeks.

Who can participate?
Low-risk nulliparous women receiving antenatal care at University Malaya Medical Centre (UMMC) between 34+0 and 36+6 weeks of pregnancy at recruitment.

What does the study involve?
Participants will be randomly assigned to one of two groups. The intervention group will receive an evidence-based information leaflet about elective induction at 39 weeks at 34+0–36+6 weeks and may read and discuss it at home. The control group will receive routine antenatal care without the leaflet at this stage.

At 37+0–38+6 weeks, both groups will receive the same leaflet and standardized counselling about induction at 39 weeks and expectant management. Participants will then complete a questionnaire assessing their decision-making experience. The main outcome is whether they accept or decline an appointment for elective induction at 39 weeks. Decision quality, maternal satisfaction, actual labour management, and maternal and neonatal outcomes will also be assessed.

What are the possible benefits and risks of participating?
Participants may find the information helpful in understanding their options regarding induction of labour. However, there is no guarantee of direct personal benefit. There are no expected physical risks from participating. The main inconvenience is the time required to read the information and complete the questionnaires.

Where is the study run from?
The University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia.

When is the study starting and how long is it expected to run for?
Participant recruitment will begin after the required ethical and regulatory approvals and prospective trial registration have been completed. Individual participation is expected to last approximately 4–8 weeks, from recruitment at 34–36+6 weeks until discharge after delivery.

Participant recruitment is planned from 1 September 2026 to 1 May 2027, with the study expected to be completed by 31 May 2027. Individual participation will last approximately 4–8 weeks, from recruitment at 34–36+6 weeks of pregnancy until discharge from hospital after delivery.

Who is funding the study?
The study is funded by the Department of Obstetrics and Gynaecology, University Malaya Medical Centre (UMMC).

Who is the main contact?
Dr Siti Nurafiqah Hanani Binti Shiekh Anuar, Department of Obstetrics and Gynaecology, University Malaya Medical Centre (UMMC), hanani.anuar@ummc.edu.my

Contact information

Type(s)
Principal investigator

Contact name
Dr Siti Nurafiqah Hanani Shiekh Anuar

Contact details
Department of Obstetric and Gynaecology, University Malaya Medical Centre
Kuala Lumpur
Malaysia
59100
+60 0172033201
hanani.anuar@ummc.edu.my

Type(s)
Scientific

Contact name
Prof Peng Chiong Tan

Contact details
Department of Obstetric and Gynaecology, University Malaya Medical Centre
Kuala Lumpur
Malaysia
59100
+60 0123052970
tanpengchiong@yahoo.com

Type(s)
Public

Contact name
Dr Siti Nurafiqah Hanani Shiekh Anuar

Contact details
Department of Obstetric and Gynaecology, University Malaya Medical Centre
Kuala Lumpur
Malaysia
59100
+60 0172033201
hananianuar19@gmail.com

Additional identifiers

Study information

Scientific Title
Impact of advance provision of an evidence-based information leaflet on women's decision regarding elective induction of labour at 39 weeks among low-risk nulliparous women: a randomized controlled trial

Acronym
AHEAD-IOL

Study objectives
Primary objective: To determine whether advance provision of an evidence-based information leaflet regarding elective induction of labour at 39 weeks influences women's decision to accept or decline an appointment for elective induction of labour at 39 weeks, compared with provision of the same information at the time of routine antenatal counselling.

Secondary objectives: To compare decision quality, maternal satisfaction with labour and birth experience, actual labour management, and maternal and neonatal outcomes between the intervention and control groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/01/2026, Universiti Malaya Medical Center-Medical Research Ethics Committee (UMMC-MREC) (Medical Research Ethics Unit (MREU) 3rd Floor, Main Tower Universiti Malaya Medical Centre Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60379493209; ummc-mrec@ummc.edu.my), ref: 2025823-15515

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Decision-making regarding elective induction of labour at 39 weeks versus expectant management among low-risk nulliparous women

Interventions
Randomisation
Participants will be randomly allocated in a 1:1 ratio using a computer-generated randomisation sequence. Variable block sizes of four, six and eight will be used. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared by an independent individual who is not involved in participant recruitment, intervention delivery or outcome assessment. Due to the nature of the intervention, participants and healthcare providers cannot be blinded to group allocation.

Intervention group:
Participants will receive a bilingual, evidence-based information leaflet regarding elective induction of labour at 39 weeks at recruitment, between 34+0 and 36+6 weeks' gestation. The leaflet provides balanced information regarding elective induction at 39 weeks and expectant management, including benefits and risks, ARRIVE trial findings, methods of induction, pain relief options, and maternal and neonatal outcomes. Participants will be encouraged to read the leaflet at home and may discuss the information with their partner or family members.

Control group:
Participants will receive routine antenatal care without the study information leaflet at recruitment. At the routine antenatal follow-up visit between 37+0 and 38+6 weeks' gestation, participants in both groups will receive the same evidence-based information leaflet and standardized counselling regarding elective induction of labour at 39 weeks versus expectant management.

Intervention Type
Behavioural

Primary outcome(s)
1. Decision to accept or decline an appointment for elective induction of labour at 39 weeks following standardized counselling measured using a structured Case Report Form (CRF); researcher records participant's decision as accept / do not accept at immediately after standardized counselling and questionnaire at 37+0–38+6 weeks' gestation

Key secondary outcome(s)
1. Decision quality assessed across 3 domains: Knowledge Adequacy, Perceived Time Pressure, and Control Over Decision-Making measured using 0–10 Visual Numerical Rating Scale (VNRS) items, at immediately after standardized counselling at 37+0–38+6 weeks' gestation, following completion of the same evidence-based information leaflet

2. Maternal satisfaction with labour and birth experience measured using three 0–10 Verbal Numerical Rating Scale (VNRS) items at following delivery and before hospital discharge

3. Actual labour management received following the participant's decision regarding elective induction of labour at 39 weeks measured using data collected from the medical record and recorded in the CRF at following delivery, based on the final obstetric management received

4. Maternal outcomes measured using data collected from the medical record and recorded in the CRF at following delivery, based on the final obstetric management received

5. Neonatal outcomes measured using data collected from the medical record and recorded in the CRF at following delivery, based on the final obstetric management received

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Nulliparous woman (no previous pregnancy beyond 22 weeks' gestation)
3. Singleton pregnancy
4. Gestational age between 34+0 and 36+6 weeks at recruitment
5. Cephalic presentation
6. Intact membranes
7. Low-risk pregnancy without known maternal, fetal, or obstetric complications requiring planned delivery before 39 weeks
8. Able to read and understand English or Malay
9. Able and willing to provide written informed consent

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Previous caesarean delivery or previous uterine surgery contraindicating labour
2. Contraindication to vaginal birth (e.g., placenta praevia, major uterine anomaly)
3. Current indication for immediate induction of labour or emergency delivery
4. Planned elective induction of labour or caesarean delivery for maternal or fetal indications
5. Major congenital fetal anomaly
6. Non-reassuring fetal status, including suspected fetal growth restriction (FGR), severe small-for-gestational-age (SGA) fetus requiring planned delivery, abnormal fetal surveillance (e.g., abnormal umbilical artery Doppler or cardiotocography), or other fetal conditions requiring obstetric intervention
7. Regular uterine contractions suggestive of established labour
8. Maternal medical disorders requiring intervention or planned delivery (e.g., pre-existing diabetes mellitus, gestational diabetes requiring medication, chronic hypertension, gestational hypertension, pre-eclampsia)
9. Inability to read or understand English or Malay

Date of first enrolment
01/09/2026

Date of final enrolment
01/05/2027

Locations

Countries of recruitment
Malaysia

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type

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

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			24/08/2026	No	No
Other files	version 3	19/06/2026	24/08/2026	No	No
Other files	version 3	19/06/2026	24/08/2026	No	No
Participant information sheet	version 3	19/06/2026	24/08/2026	No	Yes
Protocol file	version 3	19/06/2026	24/08/2026	No	No