STUDY PROTOOCOL

<PROTOCOL TITLE: IMPACT OF PERINEAL BODY LENGTH ON THE EXTENT OF PERINEAL INJURY DURING LABOUR>

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CONTENTS

TOPIC	PAGE
List of Abbreviations	
Research Synopsis	
Introduction	
Hypothesis	
Potential Benefits	
Potential Risk	
Primary Objectives	
Secondary Objectives	
Significance of Study	
Study Outcome	
Study Design	
Study Population	
Sample Size	
Inclusion Criteria	
Exclusion Criteria	
Proposed Study Duration	
Study Variables	
Operational Definitions	
Potential Covariates and Confounding Factors	
Measurement Protocol of Perineal Body Length	
Data Collection Procedure	
Data Collection Form	
Data Management	
Statistical Analysis	
Sampling Method	
Ethical Considerations	
Study Flow	
Patient Information Sheet	
Informed Consent	
References	

LIST OF ABBREVATIONS

PBL	**Perineal Body Length**
OASI	**Obstetric Anal Sphincter Injury**
SVD	**Spontaneous Vaginal Delivery**
VAD	**Vacuum Assisted Delivery**
LSCS	**Lower Segment Caesarean Section**

RESEARCH SYNOPSIS

Study Title	**Prospective Observational Cohort Study – Impact Of Perineal Body Length On the Extent Of Perineal Injury During Labour**
Study Population	**Women admitted to labour room Hospital Tuanku Ja'afar, Seremban during the first stage of labour**
Study Design	**A prospective observational cohort study – all eligible women are recruited during first stage of labour and their perineal body length will be measured and they will be followed up till delivery.**
Primary Objective	**To determine the association between perineal body length and the extent of perineal injury among women undergoing vaginal delivery at Hospital Tuanku Ja'afar, Seremban**
Secondary Objective	**1. To determine the association between perineal body length and the occurrence of obstetric anal sphincter injury (OASI).** **2. To determine the association between perineal body length and the degree of perineal tear.** **3. To determine the association between perineal body length and the occurrence of episiotomy** **4. To determine the association between maternal, obstetric and neonatal factors and the extent of perineal injury** **5. To determine the association between maternal, obstetric and neonatal factors and OASI** **6. To explore whether a clinically relevant perineal body length threshold can be identified for predicting extensive perineal injury and/or OASI.**
Study outcome	**Primary Outcome: Extent of perineal injury, defined as the highest degree of perineal tissue disruption sustained during vaginal delivery and classified as intact perineum, first-degree, second-degree/episiotomy or Obstetric anal sphincter injury (3A, 3B, 3C or fourth-degree tear).** **Secondary Outcome: OASI**
Sample Size	**815 (1600 screened , aiming for a sample size of 815- 820)**
Study Duration	**19th October 2026 – 31st October 2027**

Introduction

Perineal trauma is one of the common consequences of vaginal childbirth and may range from an intact perineum or minor first-degree injury to more extensive perineal trauma involving the anal sphincter complex. The extent of perineal injury is an important maternal outcome as more severe injuries may be associated with short- and long-term morbidity.

Obstetric anal sphincter injury (OASI), comprising third- and fourth-degree perineal tears, is a particularly significant form of perineal trauma. OASI may result in maternal complications including anal incontinence, perineal pain, dyspareunia and psychological morbidity. Identifying potentially modifiable or recognisable risk factors for OASI and extensive perineal trauma is therefore important in obstetric practice.

The anatomy of the maternal perineum may influence the degree of tissue stretching and trauma during vaginal birth. Perineal body; a fibromuscular mass located at the midline at the junction of urogenital triangle and anal triangle. The perineal body serves as a central convergence point where fibers of several muscles interlace and overlap. These include the bulbospongiosus, external anal sphincter, both the superficial and deep transverse perineal muscles, as well as smooth and skeletal muscle strands from the external urethral sphincter, levator ani muscles, and the muscular layers of the rectum. Its length is measured from the posterior fourchette to the center of the anal orifice. The usual length of perineal body is usually between 3.5 to 4cm.

The perineal body place an important role in maintaining the integrity of the pelvic floor. During second stage of labour, the left and right puboperineal muscles, with the perineal body interposed, are arranged in series to form a sling in which a baby's head must stretch enough to be able to pass through. Perineal injury during labour related to perineal body is known to cause major pelvic floor dysfunction and later complicate as pelvic organ prolapse.

Previous studies have suggested that a shorter perineal body may be associated with an increased risk of severe perineal trauma and OASI. However, the findings across different populations have not been consistent and there is limited local data regarding the relationship between perineal body length and perineal trauma among women delivering vaginally in Malaysia.

There is therefore a need for local data to determine whether perineal body length is associated with the severity of perineal trauma among women undergoing vaginal delivery at Hospital Tuanku Ja’afar, Seremban. A better understanding of this relationship within the local obstetric population may help determine whether perineal body length is a clinically relevant anatomical factor associated with the extent of perineal injury.

Therefore, this study aims to determine the association between perineal body length and the extent of perineal injury, with particular emphasis on obstetric anal sphincter injury, among women undergoing vaginal delivery at Hospital Tuanku Ja'afar, Seremban, Malaysia.

HYPOTHESIS

NULL Hypothesis

- There is no significant association between perineal body length and the extent of perineal injury and/or occurrence of obstetric anal sphincter injury among women undergoing vaginal delivery.

ALTERNATIVE HYPOTHESIS

- There is a significant association between perineal body length and the extent of perineal injury and/or occurrence of obstetric anal sphincter injury among women undergoing vaginal delivery.
- Shorter perineal body length is associated with greater severity of perineal injury

POTENTIAL BENEFITS

Participants may not receive direct individual benefit from participation.

However, the study may provide important local information regarding the relationship between perineal body length and perineal trauma during vaginal delivery.

The findings may contribute to improved understanding of anatomical factors associated with OASI and extent of perineal trauma.

POTENTIAL RISKS

The study is expected to involve minimal additional risk.
Measurement of perineal body length will be performed using a standardised clinical measurement technique.
No additional intervention affecting labour or delivery will be performed as part of the study.

Objectives

PRIMARY OBJECTIVE

- To determine the association between perineal body length and the extent of perineal injury among women undergoing vaginal delivery at Hospital Tuanku Ja'afar, Seremban.

SECONDARY OBJECTIVE

7. To determine the association between perineal body length and the occurrence of obstetric anal sphincter injury (OASI).
8. To determine the association between perineal body length and the degree of perineal tear.
9. To determine the association between perineal body length and the occurrence of episiotomy
10. To determine the association between maternal, obstetric and neonatal factors and the extent of perineal injury
11. To determine the association between maternal, obstetric and neonatal factors and OASI
12. To explore whether a clinically relevant perineal body length threshold can be identified for predicting extensive perineal injury and/or OASI.

SIGNIFICANCE OF THE STUDY

This study will provide local data on the relationship between perineal body length and perineal trauma among women undergoing vaginal delivery at Hospital Tuanku Ja'afar, Seremban.

If a significant association is identified, perineal body length may potentially represent an additional anatomical factor associated with the risk of extensive perineal injury and OASI.

The findings may provide a basis for future multicentre studies and investigation of preventive strategies for severe perineal trauma.

EXPECTED OUTCOME

The study aims to determine whether perineal body length is associated with the extent of perineal injury among women undergoing vaginal delivery.
It will specifically evaluate whether women with shorter perineal body lengths have a higher likelihood of sustaining more extensive perineal trauma and OASI.
The study will also investigate whether this association persists after accounting for other maternal, obstetric and neonatal risk factors.

PRIMARY EXPOSURE:

Perineal body length, measured continuously in cm.

PRIMARY OUTCOME:

Extent of perineal injury, defined as the highest degree of perineal tissue disruption sustained during vaginal delivery and classified as intact perineum, first-degree, second-degree/episiotomy or Obstetric anal sphincter injury (3A, 3B, 3C or fourth-degree tear).

SECONDARY OUTCOME:

Obstetric Anal Sphincter Injury (OASI)

STUDY DESIGN

This will be a **prospective observational cohort study**.

STUDY SETTING

The study will be conducted in Department of Obstetrics and Gynaecology, Hospital Tuanku Ja'afar, Seremban, Negeri Sembilan, Malaysia

STUDY POPULATION

The study population will consist of women aged 18 years and above, admitted in labour at ≥37+0 weeks of gestation, with a singleton cephalic pregnancy, who subsequently undergo vaginal delivery at Hospital Tuanku Ja'afar, Seremban.

SAMPLE SIZE

The sample size was determined based on the anticipated association between perineal body length (PBL) and the extent of perineal injury, which is the primary outcome of this study. The extent of perineal injury will be analysed as an ordinal outcome, classified as intact perineum, first-degree tear, second-degree tear/episiotomy, and obstetric anal sphincter injury (OASI).

Local data from Hospital Tuanku Ja'afar, Seremban, for 2025 demonstrated 3,742 vaginal deliveries. The distribution of perineal outcomes was 510 (13.63%) intact perineum, 1,983 (52.99%) first-degree tears, 354 (9.46%) second-degree tears, 890 (23.78%) episiotomies, and 5 (0.13%) cases of OASI. For the purpose of the primary ordinal analysis, second-degree tears and episiotomy will be grouped into the same category, resulting in the following anticipated outcome distribution: intact perineum 13.63%, first-degree tear 52.99%, second-degree tear/episiotomy 33.24%, and OASI 0.13%.

A recently published prospective cohort study evaluating perineal body length and severe perineal trauma included 495 women and demonstrated a significant association between shorter PBL and severe perineal trauma. The reported mean PBL was 3.39 ± 0.44 cm among women with severe trauma compared with 3.88 ± 0.49 cm among women without severe trauma. These findings support the anticipated association between PBL and perineal injury severity in the present study.

Because the local incidence of OASI is very low (5 cases among 3,742 vaginal deliveries; 0.13%), OASI alone was not selected as the basis for the primary sample-size calculation. A sample based solely on OASI would require a substantially larger number of participants and would provide insufficient outcome events for reliable multivariable modelling. OASI will therefore be analysed as a secondary and exploratory outcome.

For the primary analysis, an **ordinal logistic regression model** with PBL as a continuous predictor was considered using the local distribution of perineal injury categories. Assuming a conservative effect corresponding to an odds ratio of approximately 1.22 per one standard deviation change in PBL, a minimum sample of approximately 731 evaluable participants is estimated to provide 80% statistical power at a two-sided significance level of 0.05.

To account for approximately 10% of participants with incomplete PBL measurements or incomplete clinical outcome data, the required recruitment is inflated as follows:

731 ÷ 0.90 = 812 participants

Therefore, the study will aim to recruit approximately **810–815 women who subsequently undergo vaginal delivery and have complete outcome data available for analysis**.

The sample size is intended to provide adequate statistical power for the primary analysis examining the association between PBL and the overall extent of perineal injury. The study is not specifically powered to detect an association between PBL and OASI because of the very low local incidence of OASI. Any analysis involving OASI will therefore be considered secondary and exploratory.

INCLUSION CRITERIA

Participants must fulfil all the following criteria:

1. Maternal age ≥18 years
2. Gestational age ≥37+0 weeks
3. Singleton pregnancy
4. Cephalic presentation
5. Admitted in labour and subsequently undergoing vaginal delivery

EXCLUSION CRITERIA

Participants will be excluded if they have:

1. Caesarean section
2. Non-cephalic presentation
3. Preterm delivery <37+0 weeks
4. Multifetal pregnancy

PROPOSED STUDY DURATION

- 1 year (Start in 19th October 2026 -31st October 2027)

STUDY VARIABLES
INDEPRENDENT VARIABLE

- Perineal body length measured in centimetres
- Perineal body length will be analysed both as a continues variable and where appropriate categorised into clinically meaningful group.

Primary Dependent Variable

Extent of Perineal Injury

Extent of Perineal Injury will be categorised as:

- Intact perineum
- First-degree perineal tear
- Second-degree perineal tear or episiotomy
- Obstetric anal sphincter injury (OASI)

For the purposes of this study OASI will include:

- 3A tear
- 3B tear
- 3C tear
- 4the degree tear

Secondary Dependant Variable

Obstetric Anal Sphincter Injury

OASI will be recorded as:

- YES
- NO

Where OASI is present, the degree will be further classified as:

- 3A tear
- 3B tear
- 3C tear
- 4the degree tear

Buttonhole Tear

Buttonhole tear will be recorded as a **separate variable**:

- Yes
- No

A buttonhole tear will not be included as a mutually exclusive category within the overall classification of perineal injury because it may occur concurrently with another perineal tear, including OASI

OPERATIONAL DEFINITIONS

Perineal body length

Perineal body length is defined as the midline distance, measured in centimetres, between the **posterior fourchette and the anterior margin of the anus**, measured during the **first stage of labour**, during the very first vaginal examination performed in labour room prior to full cervical dilatation and active pushing.

A standardised measurement technique and timing of measurement will be used for all participants.

Extent of perineal injury

The extent of perineal injury will refer to the highest degree of perineal tissue disruption sustained during vaginal delivery classified according to the degree of perineal tear which is intact perineum, first degree, second degree/episiotomy or Obstetric Anal Sphincter Injury.

Obstetric anal sphincter injury

OASI will refer to third- and fourth-degree perineal tears involving the anal sphincter complex, classified into 3A, 3B, 3C and fourth-degree tears.

Episiotomy

Episiotomy will be recorded separately as a binary variable:

- Yes
- No

For the purpose of categorising the extent of tissue injury, an episiotomy without additional higher-grade spontaneous perineal trauma will be grouped with second-degree perineal injury.

POTENTIAL COVARIATES AND CONFOUNDING FACTORS

The following variables will be collected and considered as potential covariates and confounding factors in the analysis:

Maternal Factors

- Maternal age
- Height
- Weight
- BMI
- Gravity
- Parity
- Previous caesarean delivery

Pregnancy and labour factors

- Gestational age
- Augmentation of labour
- Duration of first stage of labour
- Duration of second stage of labour
- Fetal position

Delivery Details

- Mode of delivery
- Spontaneous vaginal delivery
- Instrumental Delivery
- Vacuum Delivery
- Forceps Delivery
- Episiotomy

Neonatal Factors

- Birth Weight

Measurement Protocol of Perineal Body Length

Perineal body length is defined as the midline distance, measured in centimeters, between the **posterior fourchette and the anterior margin of the anus.**

Timing: Done during First stage of labour – during the very first vaginal examination in labour room prior to full cervical dilatation and active pushing.

Position: Participants will be placed in dorsal lithotomy position for the measurement

Anatomical Landmarks: midline distance, measured in centimeters, between the **posterior fourchette and the anterior margin of the anus**

Instruments: A single-use wooden tongue depressor, pre-marked with measurements from 0 to 6 cm at 0.1-cm intervals. The measurement will be recorded to the nearest 0.1 cm. A new tongue depressor will be used for each participant.

Units: Centimetres

Observer: The measurement will be performed **once** by the **medical doctor conducting the first vaginal examination** upon the participant's admission to the labour room. All clinicians involved in data collection will undergo standardized training using the same anatomical landmarks and measurement technique before commencement of the study.

Data Collection Procedure

Eligible women admitted in labour will be assessed against the inclusion and exclusion criteria.

After recruitment, baseline demographic and obstetric characteristics will be recorded.

Perineal body length will be measured according to the standardised study protocol.

Following vaginal delivery, the following outcomes will be documented:

- Mode of vaginal delivery
- Birth weight
- Episiotomy
- Degree of perineal injury
- Presence of OASI
- Degree of OASI
- Presence of buttonhole tear

All perineal injuries will be assessed and documented by the attending clinician according to the standard clinical classification.

Data will subsequently be entered into a structured electronic data collection form

DATA COLLECTION FORM

The proposed data collection form will contain the following sections:

1st Section

- Date of Admission to labour room
- Perineal Body Length
- Mode of Delivery

Demographics

- Maternal Age in Years
- Height in Metres
- Weight in Kg
- Gravida
- Para
- Number of Abortions
- Previous history of caesarean delivery
- Gestational age in weeks

Labour details

- Augmentation of labour with Oxytocin --YES or NO
- Epidural -YES or NO
- Analgesic
- Duration of First Stage of Labour in Hours and Minutes
- Duration of Second Stage of Labour in Hours and Minutes
- Fetal Position
- Estimated Fetal Weight in Grams
- Head Circumference in centimetres
- Episiotomy if was given --YES or NO
- Episiotomy type
- Perineal Protection Technique
- Perineal Injury Degree
- Obstetric Anal Sphincter Injury if present – YES or NO
- Type of Obstetric Anal Sphincter
- Buttonhole if present -YES or NO
- Other Genital Tract Injury
- Vaginal Wall Hematoma if present -YES or NO
- Perineal Repair if done - -YES or NO
- Perineal Repair if done in OT -YES or NO
- Estimated Blood Loss

- Blood Transfusion if given -YES or NO

DATA MANAGEMENT

Each participant will be assigned a unique Participant Study Identification Number (PSID).

Identifiable information will be limited to the minimum required for the study and will only be accessible to authorised members of the research team.

Electronic data will be password protected.

The final analytical dataset will use the PSID rather than direct patient identifiers wherever possible.

STATISTICAL ANALYSIS

Statistical analysis will be performed using SPSS or equivalent statistical software.

Descriptive analysis

- Maternal, obstetric, neonatal and perineal characteristics will be summarised.
- Continuous variables will be presented using mean and standard deviation or median and interquartile range depending on data distribution.
- Categorical variables will be presented as frequencies and percentages.

Analysis of primary outcome

The association between perineal body length and the extent of perineal injury will be assessed.

Perineal injury will be treated as an ordinal outcome where appropriate:

- **Intact → First degree → Second degree/episiotomy → OASI (3A, 3B, 3C or 4th degree**

  A more appropriate primary analysis would likely be **ordinal logistic regression**, with:

  - **Outcome:** injury severity
  - **Main predictor:** PBL in cm

  Episiotomy will be recorded as a separate binary variable. For the purpose of the ordinal classification of overall perineal tissue disruption, an episiotomy without concurrent higher-grade spontaneous perineal trauma will be classified within the second-degree category.

- **Analysis of OASI**

  The association between perineal body length and OASI will be assessed using appropriate univariate analysis.

  Multivariable logistic regression will be performed, where appropriate, to determine whether perineal body length is independently associated with OASI after adjustment for relevant confounding variables.

Potential confounders may include:

- Maternal Age
- BMI
- Parity
- Birth weight
- Instrumental Delivery
- Episiotomy
- Gestational Age
- Other clinically relevant factors

Secondary analysis

The relationship between perineal body length and individual OASI grades (3A, 3B, 3C and fourth degree) will be explored where sample size permits.
ROC curve analysis may be performed to assess whether perineal body length has discriminatory ability for predicting OASI and to explore a potential threshold.
A p-value of <0.05 will be considered statistically significant.

SAMPLING METHOD

A consecutive sampling method will be used. All women who meet the eligibility criteria and provide informed consent will be recruited consecutively upon admission to the labour room during the study period until the required sample size is achieved.

Perineal body length will be measured at the first vaginal examination in the first stage of labour, prior to full cervical dilatation and active pushing. Participants will subsequently be followed until delivery. Women who undergo caesarean section will be excluded from the final analysis, while those who subsequently undergo vaginal delivery will be included in the final analysis.

ETHICAL CONSIDERATIONS

Ethical approval will be obtained from the National Medical Research Centre of Malaysia and the Clinical Research Centre of Hospital Tuanku Ja'afar, Seremban, Negeri Sembilan - research ethics authorities before commencement of the study.

Participation will be voluntary and informed consent will be obtained according to the approved research protocol.

Participation will not alter the participant's clinical management.

All clinical decisions regarding mode of delivery, episiotomy and instrumental delivery will remain at the discretion of the treating obstetric team and will follow established clinical indications and institutional guidelines.

Participant confidentiality will be maintained throughout the study.

STUDY FLOW

Women admitted in labour in Hospital Seremban

Eligibility Assessment

Age ≥18 years • Singleton pregnancy • Cephalic presentation • Gestational age ≥37+0 weeks •Admitted in labour and subsequently undergoing vaginal delivery

Eligible

Proceed with study

Not Eligible

Exclude from study

Preterm • Non-cephalic • Multifetal

Informed consent / recruitment

Prospective enrolment

Baseline data collection

Maternal demographics • BMI • Gravidity/parity • Gestational age

Standardized Measurement

Perineal body length recorded in centimeters

Include if - Vaginal delivery

Spontaneous or Instrumental Delivery

Exclude if LSCS

Post-delivery Assessment

Episiotomy • Degree of perineal injury • OASI grade • Buttonhole tear • Birth weight

Study outcomes

Extent of perineal injury

Intact → 1st degree → 2nd degree/episiotomy → OASI

OASI: 3A • 3B • 3C • 4th degree

Buttonhole tear recorded separately

Statistical Analysis

Association between perineal body length and extent of perineal injury / OASI, with adjustment for relevant confounders