Informed Consent Form

Effect of Amniotomy in early Labor on duration of Labor in primigravida at term pregnancy: A Randomized controlled trial.

IRB NUMBER: IHHN_IRB_2025_05_019

DATE: 29-09-2025 to 28-09-2026

APPROVED by
IHHN Institutional Review Board
29 Sep 25 **28 Sep 26**
Approved on Expires on
DO NOT USE THIS FORM AFTER APPROVAL EXPIRY

IRB NUMBER: IHHN_IRB_2025_05_019
PI: DR. BUSHRA IQBAL
PI: VERSION DATE: 2 SEP 25
RCT CONSENT FORM

Study Title: Effect of Amniotomy in early Labor on duration of Labor in primigravida at term pregnancy: A Randomized controlled trial.

Assalam-o-alaikum, my name is Dr. Bushra Iqbal and I am working as doctor in gynae department of Indus hospital (Recep Tayyip Erdogan Hospital, Muzaffargarh). I am conducting a research study on "Effect of Amniotomy in early Labor on duration of Labor in primigravida at term pregnancy: A Randomized controlled trial" under supervision of Dr Samiea Parveen. I would like to ask you for your consent to participate in a research study. Your participation is voluntary and you have the right to choose whether to participate or not participate in this study. If you decide to participate and later change your mind, you may do so without any penalty or consequences to your treatment here.

Purpose of research project:

In this study we will intentionally rupture the amniotic sac in early labour and will check the duration of labour either it is helpful in shortening the duration of labour or not, and we will compare it with those women in which amniotic sac will be kept intact. In this way we will able to learn that which action is more helpful in shortening the duration of labour during childbirth. In this study we will enroll 60 women. We will divide patients in 2 groups. ln group A, amniotic sac will be intentionally ruptured during labour while in group B, amniotic sac will be left intact untill delivery.

What you will be asked to do in this study

If you agree to be part of this study, you will be placed in one of two groups randomly.

GROUP A: Amniotic sac will be intentionally ruptured during labour.

GROUP B: Amniotic sac will be left intact untill delivery.

Privacy: We assure you that your research information will be kept secret. We will use ID numbers instead of your name. Your name will not be given to anyone without your consent. Your doctor and researchers from Indus Hospital will be able to look at your medical records. We may also publish this research for scientific purposes.

Risks and Discomfort; There will be no added risk to you in this study. The intensity of pain may increase little after intentionally rupturing of amniotic sac. but doctors will be there to monitor you.

Benefits: In this study we will able to learn that which action during childbirth is more helpful in shortening the duration of labour and in future we can manage women in labour more effectively.

Alternatives: You have the choice of not being part of the study and your treatment will continue as usual.

Cost or payment for taking part in research: You do not have to pay for taking part in this study nor will you receive any money.

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Who do I call if have questions or problem?

If you have questions about this research, you can contact Dr. Bushra Iqbal at the Indus Hospital, (Mobile: 03066620825)

If you have questions about your rights in a research study as a volunteer, call or contact the Indus Hospital & Health Network-IRB office between office hours on Monday to Friday 9am - 5pm (Mobile 0304-9264093)

SIGNATURES
If you agree to participate in this study, please sign/thumb impression this form. You will receive a copy of this form.

Sign of study volunteer/participant: _____

Date: _____

Sign of person taking consent: _____

Date: _____

Sign of witness: _____ (if applicable)

Date: _____