

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

THE USE OF ASSISTED PRE-PROCEDURAL ULTRASONOGRAPHY VERSUS LANDMARK TECHNIQUE IN IDENTIFYING EPIDURAL SPACE IN WOMEN REQUESTING LABOR ANALGESIA

Protocol summary

Study aim

To compare whether the use of ultrasonography (USG) is superior to blind landmark technique in correctly identifying epidural space in pregnant patients requesting labor analgesia through epidural catheter

Design

Prospective observational study

Settings and conduct

This prospective observational study was carried out at the Department of Anesthesiology, Combined Military Hospital from after approval from the ethical review board

Participants/Inclusion and exclusion criteria

Inclusion criteria included all ASA I and II patients between 20-35 years of age presenting in labor after achieving term. Exclusion criteria included patients with history of back pain, surgeries of the spine, on-going medical treatment for backache, patients unwilling to be included in the study, patients with coagulation disorders or on anti-coagulants and BMI greater than 35 kg/m².

Intervention groups

A total of 250 patients were included in the study protocol divided into Group U (n=125) and Group L (n=125). Primary variables measured were mean number of tries for epidural insertion (taking the needle out and then re-introduction), mean number of needle re-directions (without taking out from skin), difference between actual measured needle length (AML) versus USG measured needle length (UML) and number of dural punctures between the USG and landmark group

Main outcome variables

Primary variables measured were mean number of tries for epidural insertion (taking the needle out and then re-introduction), mean number of needle re-directions (without taking out from skin), difference between actual measured needle length (AML) versus USG measured needle length (UML) and number of dural punctures

between the USG and landmark group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230819059186N1**

Registration date: **2023-08-25, 1402/06/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-25, 1402/06/03**

Update count: **0**

Registration date

2023-08-25, 1402/06/03

Registrant information

Name

Syed Aqib Ali Shah

Name of organization / entity

Combined Military Hospital Rawalpindi Punjab
pakistan

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-18, 1402/01/29

Expected recruitment end date

2023-10-18, 1402/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

THE USE OF ASSISTED PRE-PROCEDURAL
ULTRASONOGRAPHY VERSUS LANDMARK TECHNIQUE IN
IDENTIFYING EPIDURAL SPACE IN WOMEN REQUESTING
LABOR ANALGESIA

Public title

THE USE OF ASSISTED PRE-PROCEDURAL
ULTRASONOGRAPHY VERSUS LANDMARK TECHNIQUE IN
IDENTIFYING EPIDURAL SPACE IN WOMEN REQUESTING
LABOR ANALGESIA

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

included all ASA I and II patients between 20-35 years of
age presenting in labor after achieving term.

Exclusion criteria:

patients with history of back pain, surgeries of the spine,
on-going medical treatment for backache, patients
unwilling to be included in the study, patients with
coagulation disorders or on anti-coagulants and BMI
greater than 35 kg/m2.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **250**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical committee/ institutional review board
Combined Military Hospital Rawalpindi

Street address

Street 22 Saddar Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2023-04-17, 1402/01/28

Ethics committee reference number

429

Health conditions studied**1****Description of health condition studied**

Labor Analgesia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Primary variables measured were mean number of tries
for epidural insertion (taking the needle out and then re-
introduction), mean number of needle re-directions
(without taking out from skin), difference between actual
measured needle length (AML) versus USG measured
needle length (UML) and number of dural punctures
between the USG and landmark group.

Timepoint

Primary variables measured were mean number of tries
for epidural insertion (taking the needle out and then re-
introduction), mean number of needle re-directions
(without taking out from skin), difference between actual
measured needle length (AML) versus USG measured
needle length (UML) and number of dural punctures
between the USG and landmark group.

Method of measurement

The patients were divided into the ultrasonography
group (Group U) (n=125) and the landmark group (Group
L) (n=125). Primary variables measured were mean
number of tries for epidural insertion (taking the needle
out and then re-introduction), mean number of needle
re-directions (without taking out from skin), difference
between actual measured needle length (AML) versus
USG measured needle length (UML) and number of dural
punctures between the USG and landmark group.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Patients in Group L followed the
standard blind landmark technique for insertion of the

epidural catheter in the L4-L5 space under strict aseptic measures in the procedure room in the sitting position. In case of dural puncture, the space above was then identified and epidural was inserted.

Category

Treatment - Other

2**Description**

Intervention group 2: Patients in Group U were also prepped in the recovery room under aseptic measures for the USG procedure. A standard curvy-linear probe was placed and the parasagittal view of the L5-S1 space was identified and L4-L5 space was identified by counting upwards. After correct placement and confirmation of the space, the probe was then rotated, and the transverse view was obtained. Epidural space was then identified between the ligamentum flavum and dural space.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Anesthesia department of Combined Military Hospital, Rawalpindi Punjab Pakistan

Full name of responsible person

Syed Aqib Ali Shah

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22 No Street Saddar Rawalpindi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Combined Military Hospital Rawalpindi Pakistan

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Combined Military Hospital Rawalpindi Pakistan

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Combined Military Hospital Rawalpindi Pakistan

Full name of responsible person

Syed Aqib Ali Shah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available