Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

THE USE OF ASSISTED PRE-PROCEDURAL ULTRASONOGRAPHY VERSUS LANDMARK TECHNIQUE IN IDENITIFYING 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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Email address

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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 IDENITIFYING EPIDURAL SPACE IN WOMEN REQUESTING LABOR ANALGESIA

Public title
THE USE OF ASSISTED PRE-PROCEDURAL ULTRASONOGRAPHY VERSUS LANDMARK TECHNIQUE IN IDENITIFYING 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

Street address

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

Dr Rashid Iqbal

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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

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Person responsible for updating data

Contact
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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