

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Randomized clinical trial of comparing the results of routine lumbar puncture (LP) and ultrasound assisted lumbar puncture via emergency physicians in patients referring to emergency department

Protocol summary

Summary

(1) Objectives: Our aim in this study is to evaluate the role of ultrasound in increasing the rate of success in performing lumbar puncture procedure in patients referring to emergency department. (2) design: In this study, 50 patients referring to Emergency department, Imam Reza Hospital, Tabriz will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent. Patients need a lumbar puncture for definite diagnosis of the disease. (3) Setting and conduct: Patients will be randomly divided to groups of 25. For randomization, we will use computerized randomization with Excel software. Inclusion criteria are age more than 18 years old and the need to perform lumbar puncture for a definite diagnosis of the disease. Exclusion criteria are contraindications for lumbar puncture such as infections in the site, spinal vertebrae malformations and surgeries on vertebrae. (4) Intervention: Patients will be divided into two groups of routine lumbar puncture and real time ultrasound assisted lumbar puncture. In intervention group, the route will be first defined and confirmed by using ultrasound. In the other group lumbar puncture will be performed as routine and without using other instruments. To prevent bias, all lumbar puncture will be done by an emergency resident. (5) Main outcome measures: Time to perform the procedure, success rate, number of tries to perform a successful procedure, rate of complications, rate of picore and drytap will be recorded during and at the end of procedures.

General information

Acronym

LP - Lumbar Puncture

IRCT registration information

IRCT registration number: **IRCT2013102511067N3**

Registration date: **2013-11-06, 1392/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-06, 1392/08/15

Registrant information

Name

Mahboub Pouraghaei

Name of organization / entity

Tabriz University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-09-21, 1392/06/30

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of comparing the results of

routine lumbar puncture (LP) and ultrasound assisted lumbar puncture via emergency physicians in patients referring to emergency department

Public title

Evaluating the effects of using an ancillary method for performing lumbar puncture

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Being more than 18 years old; need to perform a lumbar puncture for definite diagnosis of disease. Exclusion criteria: Contraindications for lumbar puncture such as infections in the site, spinal vertebrae malformations and surgeries on vertebrae.

Age

From **18 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Ethics committee, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Postal code

Approval date

2013-07-21, 1392/04/30

Ethics committee reference number

7/4/3275

Health conditions studied

1

Description of health condition studied

Lumbar puncture

ICD-10 code

G97

ICD-10 code description

Postprocedural disorders of nervous system, not elsewhere classified

Primary outcomes

1

Description

Time to perform the procedure

Timepoint

At the end of procedure

Method of measurement

By performer of the procedure

2

Description

Number of tries to perform a successful procedure

Timepoint

At the end of procedure

Method of measurement

By performer of the procedure

3

Description

Success rate

Timepoint

At the end of study

Method of measurement

By performer of the procedure

4

Description

rate of drytap

Timepoint

At the end of study

Method of measurement

By performer of the procedure

Secondary outcomes

1

Description

Cerebrospinal fluid leak

Timepoint

At the end of procedure and at the end of study

Method of measurement

By performer of the procedure

Intervention groups

1

Description

In intervention group, route for lumbar puncture will be defined and confirmed by using ultrasound.

Category

Diagnosis

2

Description

In control group, lumbar puncture will be performed as routine.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Moloud Balafar

Street address

Department of Emergency Medicine, Imam Reza Hospital, Daneshgah Square, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyyed Kazem Shakouri

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square, Tabriz

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Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Moloud Balafar

Position

Emergency Medicine resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mahboub Pouraghaei

Position

Assistant Professor/ Specialist in Emergency Medicine

Other areas of specialty/work

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Position

Emergency Medicine resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty