

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of effect of electro acupuncture, in providing pain relief during bone marrow aspiration and biopsy in adults

Protocol summary

Summary

INTRODUCTION: The bone marrow aspiration and biopsy (BMA/BMB) has a well-known role in diagnosing and staging of malignancies, evaluating platelet, white or red blood cell disorders, and defining various infectious diseases. It's a painful procedure. Usually it's been executed by local anesthesia (LA). Some of the clinicians use benzodiazepine in addition to local anesthesia. In spite of using local anesthesia and benzodiazepine, it's still a painful procedure. Acupuncture and its subtypes, like transcutaneous acupoint electrical stimulation (TAES), has been proved to have analgesic effect in some pains as well as in some other painful procedures. Considering the important role of BMA/BMB in diagnosis and staging of a broad spectrum of diseases, its painfulness and its need for an easy safe and fast acting pain relieving technique, and in regard to the important role of acupuncture in relieving various pains, we want to compare the pain score in the patients undergoing BMA/BMB who receive bilateral TAES in addition to LA with the ones who don't receive TAES. **METHOD:** It's a triple blind randomized clinical trial. The patients over 18 years old requiring BMA/BMB in Sayyedoshohada Hospital enter the study. They will randomly be divided into 2 groups. Each group will consist of 25 patients. Both groups will receive local anesthesia with Lidocaine. The case group will also receive TAES on LI 4 and LI 11 bilaterally, and the control group will receive placebo TAES, then both groups will determine their pain level during BMA/BMB through VAS. The mean of VAS of each group will be compared. Before executing the procedure and once during the procedure, each patient's blood pressure and pulse rate will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012082610676N1**

Registration date: **2012-09-16, 1391/06/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

Name

Omid Shokrani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1265 7678

Email address

shokrani@edc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-09-20, 1391/06/30

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of electro acupuncture, in providing pain relief during bone marrow aspiration and biopsy in adults

Public title

Evaluation of effect of electro acupuncture, in providing pain relief during bone marrow biopsy in adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients over 18 years old requiring an outpatient bone marrow biopsy, who does not have any of the following conditions will be invited to participate in the study: 1) Addiction 2) Having a pacemaker 3) History of vasovagal reaction 4) Cardiac dysrhythmias. 5) Pregnancy Exclusion criteria: The patient will be excluded and the procedure will be stopped if s/he develops vasovagal reaction during the procedure

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

UTN

Secondary trial Id

U1111-1133-9534

Registration date

2012-08-29, 1391/06/08

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences- Hezarjarib Street- Isfahan

City

Isfahan

Postal code**Approval date**

2011-05-30, 1390/03/09

Ethics committee reference number

390114

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

Pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes**1****Description**

Use of electro acupuncture or placebo

Timepoint

just before intervention

Method of measurement

electro acupuncture/placebo

Secondary outcomes**1****Description**

pain

Timepoint

once the patient feels recovered from the procedure

Method of measurement

Visual Analogue Scale

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

Electro acupuncture on the points LI4 and LI11, with the ON device in intervention group

Category

Treatment - Devices

2**Description**

Placebo electro acupuncture on the points LI4 and LI11, with the OFF device in the control group

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center

Sayedoshohada Hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Research Department of Medicine Faculty of Isfahan
University of Medical Sciences
Street address
Research Department of Medicine Faculty of Isfahan
University of Medical Sciences
City
Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Omid Shokrani
Position
Medical Student (Intern)
Other areas of specialty/work
Street address
No.28- Arg Alley- Abolhassan Esfahani Street-
Moshtagh Avval Street- Isfahan
City
Isfahan
Postal code
Phone
+98 31 1265 7678
Fax
Email
Kaizen.hiva@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Omid Shokrani
Position
Medical Student (Intern)
Other areas of specialty/work
Street address
No.28- Arg Alley- Abolhassan Esfahani Street-
Moshtagh Avval Street- Isfahan
City
Isfahan
Postal code
Phone
+98 31 1265 7678
Fax
Email
kaizen.hiva@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Omid Shokrani
Position
Medical Student (Intern)
Other areas of specialty/work
Street address
No.28- Arg Alley- Abolhassan Esfahani Street-
Moshtagh Avval Street- Isfahan
City
Isfahan
Postal code
Phone
+98 31 1265 7678
Fax
Email
kaizen.hiva@gmail.com
Web page address

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