Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Scineces

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 dysrythmias. 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 Scineces
Full name of responsible person
Research Department of Medicine Faculty of Isfahan University of Medical Scineces
Street address
Research Department of Medicine Faculty of Isfahan University of Medical Scineces
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 Scineces
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

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Name of organization / entity
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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