

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of needle changing on severity of pain induced by intramuscular injection in female patients

Protocol summary

Summary

Objectives: This study has done based on defining the impact of changing needle, in order to reduce pain on intramuscular injection. Design: This study through crossing and randomized method. Setting and conduct: The researcher extracted 5 cc of this medicine by syringe needle as code No.21, and after forcing out air through syringe needle, he changed the needle, and put the labeled code"1"(injection with needle changed or" interfering Group"), the repeated this process, but not change its needle, and Labeled it code"2" (injection without needle changed or" control Group") after that, in following he defined which code (1or 2) is used for the fist injection by Heads or Tails way. Therefore, method of injection and syringe code of second injection was contrary with the first one. Duration of second injection was 20 min after the first one. Participants including major eligibility criteria: We chose 70 female patients with intramuscular injection of Metucarbamul medicine and the age should be over 18 and under 58 years. Intervention: needle changing Main outcome measures: severity of pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062313749N1**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-23, 1395/10/03

Registrant information

Name

Amene Manavy shad

Name of organization / entity

Arvand International University

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Recruitment status

Recruitment complete

Funding source

Arvand International University - Ahvaz Jundishapur University of Medical Science , Ahvaz, Iran

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of needle changing on severity of pain induced by intramuscular injection in female patients

Public title

The effect of needle changing by intramuscular injection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The age should be over 18 and under 58 years; Holding the permission of intramuscular injection of Metocarbamul medicine; Not committing intramuscular injection within the last week; Having body mass of 19-25; Being conscious of the ill person; Non using any pain killer medicine prior to injection Exclusion

critwria: study existence of blue-dark, reddish marks and inflammation and wound in the place of injection; Having record of diabetic.

Age

From **18 years** old to **58 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Science

Street address

Ahvaz Jundishapur University of Medical Science
,Golestan , Ahvaz, Iran

City

Ahvaz

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

ajams/REC/1392/112

Health conditions studied

1

Description of health condition studied

severity of pain

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

severity of pain

Timepoint

After finishing injection,measuring patent pain

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention1: The researcher extracted 5 cc of this medicine by syringe needle as code No.21, and after forcing out air through syringe needle, he changed the needle, and put the labeled code "1"(injection with needle changed). Interfering Group.

Category

Treatment - Other

2

Description

Intervention1: The researcher extracted 5 cc of this medicine by syringe needle as code No.21, and after forcing out air through syringe needle, but not changed the needle, and put the labeled code "2"(injection without needle changed).Control Group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghan Hospital

Full name of responsible person

leila Fakharzadeh

Street address

No8,Asatid Falat Bulding, In front of Abadan international airport, Abadan, Khuzestan,Iran

City

Abadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Science Vice chancellor for research Arvand
International University

Full name of responsible person

Bahram Abdali

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Arvand international university, In front of Abadan
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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

Medical Science Vice chancellor for research Arvand
International University

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Medical Science Vice chancellor for research Ahvaz
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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

Medical Science Vice chancellor for research Ahvaz
Jundishapur University of Medical Science

Proportion provided by this source**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

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Full name of responsible person

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Position

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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