Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 3515

Email address

ami.manavy@yahoo.com

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
Street address
Arvand international university, In front of Abadan international airport
City
Abadan
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 Jundishapur University of Medical Science
Full name of responsible person
Mostafa feghihi
Street address
Ahvaz Jundishapur University of Medical Science ,Golestan Ahvaz, Iranch
City
Ahvaz
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
Arvad International University
Full name of responsible person
Bahram Abdali
Position
Medical Science Vice chancellor for research Arvand International University
Other areas of specialty/work
Street address
Arvand international univercity, In front of Abadan international airport
City
Abadan
Postal code
Phone
+98 63 1333 5364
Fax
Email
bahram_abdali@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arvand International University
Full name of responsible person
leila Fakharzadeh
Position
M.A Nursing
Other areas of specialty/work
Street address
No 8, Asatid Flalat Bulding, In front of Abadan international air port, Abadan, Khuzestan , Iran
City
Abadan
Postal code
Phone
+98 63 1333 7857
Fax
Email
fakharzadehl@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arvand International University
Full name of responsible person
Amene Manavy Shad
Position
Nursing graduate student
Other areas of specialty/work
Street address
No 742,2 nd, Golestsn, Bame Tehran building ,Tehran, Iran
City

Tehran
Postal code
Phone
+98 21 2213 3515
Fax
Email
ami.manavy@yahoo.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