Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing effects of two muscular injection methods on site-pain intensity of injection

Protocol summary

Summary

Injections are among the most frequently used medical procedures, with more than 12 billions injections administered each year world-wide. In spite of the wide use of the procedure, pain associated with injection remains an unsolved problem of the contemporary medical practice. Reducing patients' pain is important for all nurses for many reasons. Unnecessary pain can damage the nurse—patient relationship and may also lead to dangerous syncopal attacks. The aim of this study is to compare of effects of two muscular injection methods on site-pain intensity of injection in patients who refer to injections ward of Kamkar-Arabnia hospital, Qom, Iran, in 2010. In this work, 75 women with ages from 16-60 years who have penicillin injection intramuscularly in a health centre will be studied. The samples are chosen randomly divided into three groups: the first group will receive intramuscular injection with the application of the blunt pins, the second group will receive local cold therapy and the third group (the control group) will receive routine care. Pain will be tested with the visual analogue scale on a 0 (no pain)-10 (maximum pain) scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011012560N4**
Registration date: **2010-12-02, 1389/09/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-02, 1389/09/11

Registrant information

Name

Mohammad reza Yeganehkhah

Name of organization / entity

Qom University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences and Health Services

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of two muscular injection methods on site-pain intensity of injection

Public title

Comparing effects of two muscular injection methods on site-pain intensity of injection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1) Women aged 18-80 years. 2) Having order to receive Penicillin 6.3.3 as a IM injection. 3) Having no sensitivity to Penicillin. 4) Oriented to person/ place/ time/ situation. 5) Ability of patient to assess the

pain with visual analogue scale. 6) Ability of patient to looking and listening. Exclusive criteria: 1) Having pain in the injection site. 2) BMI less than18.5 and more than 30. 3) Having wound or scar in the injection site. 4) Absence of collaboration.

Age
From **16 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The sample size of the study was calculated with power of 80% and significance level of 5% according with the result of previous studies.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qom University of Medical Sciences and Health Services

Street address
Qom University of Medical Sciences and Health Services, Saheli st., Qom., Iran.

City
Qom

Postal code
37185

Approval date
2010-10-21, 1389/07/29

Ethics committee reference number
12050/34/ت

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
pain

Timepoint
Before and after intramuscular injection

Method of measurement
Visual Analogue pain Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
(1) In the first group, injections will perform with a plastic device, that consists of an oval disk (54 mm×40 mm) that supports multiple blunt pins (9 pins per cm2). In the middle of the oval support there is a hole of 5 mm of diameter. The use of the device is the following: first it is put on the skin at the injection site, then the injection needle is inserted in the hole of the device until it reaches the skin, without penetrating it; the device is then gently, but firmly, pressed onto the skin immediately prior and during the penetration of the injection needle into the skin. The device does not interfere with the needle penetration or with the drug delivery and there is no contact between the device and the injection needle.

Category
Other

2

Description
(3) In the control group, a standard injection is give with no further intervention as it is routine in most hospitals.

Category
N/A

3

Description
(2) In the second group(cold therapy), the subjects will inform that a 2—3 cm piece of ice would be placed on the injection site on the gluteal muscle for 30 s prior to injection.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamkar-Arabnia hospital
Full name of responsible person
Street address
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences and Health Services
Full name of responsible person
Ali Salimi
Street address
Saheli st.
City
Qom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University of Medical Sciences and Health Services
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
Qom University of Medical Sciences and Health Services
Full name of responsible person
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Position
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Web page address

Person responsible for updating data

Contact

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