Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of dorsogluteal local pressure and Hugo's point massage with ice on pain sevirity due to intramuscular injection

Protocol summary

Study aim
Comparison of dorsogluteal local pressure and Hugo's point massage with ice on pain sevirity due to intramuscular injection

Design
Clinical trial with control group, with parallel groups, with blinded group

Settings and conduct
The study population consisted of women who referred to the injection unit of Allameh Behlul Hospital in Gonabad.women who has inclusion criteria, after Explain the aims of the study and obtain informed consent, will be divided into intervention and control group randomly and based on the designated blocks. The conditions in the intervention and control groups will be the same. In intervention group 1, local pressure and in intervention group 2, Hugo's point massage will be done. In control group, injection is performed as usual

Participants/Inclusion and exclusion criteria
1.Informed consent to participate in the research. 2. Lack of stiffness, tenderness, and lesion at the injection site according to the patient's report. 3. No severe illness and pain duo to disease according to the patient's report. 4. No injection in that area a week ago according to the patient's report. 5. No pain before intramuscular injection. 6. Age between 18 and 50. 7. do not recive opioid and non-opioid painkiller in 2 hours before injection. 8. Don't be pregnant.

Intervention groups
For intervention group 1, a local pressure with thumb to the injection site applied until the patient feels pain for 10 seconds, then inject immediately. For intervention group 2, Hugo's point massage of right hand with ice wrapped in plastic glove and One layer cotton cloth was done Clockwise for 3 minutes, with soft and continuous pressure of 3 kg / m2, then massage is stopped for 30 seconds, and after that this intervention will be repeated twice. In control group, injection is performed as usual.

Main outcome variables
the pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191217045772N1**
Registration date: **2020-04-22, 1399/02/03**
Registration timing: **retrospective**

Last update: **2020-04-22, 1399/02/03**
Update count: **0**

Registration date
2020-04-22, 1399/02/03

Registrant information

Name
fatemeh saadati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5723 4385

Email address
saadati.f.stu@gmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-24, 1398/10/03

Expected recruitment end date
2020-02-22, 1398/12/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of dorsogluteal local pressure and Hugo's point massage with ice on pain sevirity due to intramuscular injection

Public title
Comparison of topical pressure and Hugo's point massage on pain of intramuscular injection

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
1.Informed consent to participate in the research. 2. Lack of stiffness, tenderness, and lesion at the injection site according to the patient's report. 3. No severe illness and pain duo to disease according to the patient's report. 4. No injection in that area a week ago according to the patient's report. 5. being completely alert and able to respond and determine pain based on visual pain scale 6. Having the sense of hearing, vision. 7.ability to communicate. 8. No pain before intramuscular injection. 9. Age between 18 and 50 10. do not recive opioid and non-opioid painkiller in 2 hours before injection. 11. Don't be pregnant.

Exclusion criteria:
1. Any new medical conditions that restrict muscle infusion or affect patients' pain.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **81**

Randomization (investigator's opinion)
Randomized

Randomization description
Sample allocation will be done by ABC by random assignment of permutation blocks with triple blocks.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Gonabad University of Medical Sciences

Street address
Gonabad, Asian Road Margin, Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691167975

Approval date
2019-08-02, 1398/05/11

Ethics committee reference number
IR.GMU.REC.1398.081

Health conditions studied

1

Description of health condition studied
Factors Influencing Health Status and Contacting Health Services

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain caused by intramuscular injection

Timepoint
Immediately after the intramuscular injection

Method of measurement
Visual scale of pain

Secondary outcomes

empty

Intervention groups

1

Description
For intervention group 1, a local pressure with thumb to the injection site applied until the patient feels pain for 10 seconds, then inject immediately.

Category
Prevention

2

Description
For intervention group 2, Hugo's point massage of right hand with ice wrapped in plastic glove and One layer cotton cloth was done Clockwise for 3 minutes, with soft and continuous pressure of 3 kg / m2, then massage is stopped for 30 seconds, and after that this intervention will be repeated twice

Category

Prevention

3

Description
Control group: In control group, injection is performed as usual.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Behlul Hospital of Gonabad
Full name of responsible person
Fatemeh Saadati Baghsiahy
Street address
Gonabad, Saadi St., Vahdat Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr.Shahla Khosravan
Street address
Deputy of Research and Technology, Gonabad University of Medical Sciences, Asian Road, Gonabad
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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
Gonabad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Fateme Saadati Baghsiahy
Position
MSc in Internal Surgical Nursing
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Dr. Ali Mohammadpour
Position
Member of Gonabad University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Fatemeh Saadati baghsiahy

Position

MSc Student of Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available