Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

A randomized, double-blind controlled trial study comparing the efficacy of granisetron versus lidocaine injection of trigger points in upper trapezius of patients with Myofascial Pain Syndrome referring to the AJA University Hospital

Protocol summary

Study aim
The effect of topical injections of Granisetron compared with lidocaine on pain trigger points in the upper trapezius muscle, among patients diagnosed with myofascial pain syndrome

Design
A randomized, double-blind, clinical trial with 2 intervention groups including 40 samples in blocks of 4

Settings and conduct
40 patients referred to Physical medicine and rehabilitation department of 501 Artesh hospital, divided in 2 groups randomly (1 group injection of Granisetron and other group injection of Lidocaine) then each group evaluated separately using Visual Analog Scale, Neck Disability Index and Neck Pain and disability Scale in first, one month and 3 months later.

Participants/Inclusion and exclusion criteria
Entry requirements: 1. Being at least 18 years old 2. Neck or shoulder pain complaints for at least one month 3. At least one trigger point in the upper trapezius muscle 4. Non pregnant woman 5. No prior disease (severe cystic, spine, spinal canal stenosis) 6. No history of fibromyalgia or rheumatic diseases 7. No prior history of allergy to Granisetron or lidocaine. Exclusion conditions: 1. No patient co-operation or follow up 2. Pain Aggravation (unbearable for the patient)

Intervention groups
Single administration of 1cc lidocaine (0.5% concentration) trough injection (Caspian Pharmaceutical Company). Single administration of 1cc Granisetron trough injection (Caspian Pharmaceutical Company)

Main outcome variables
Visual analogue scale; Neck Disability Index; Neck Pain and Disability Scale.

General information

Reason for update
The typographical error instead of the two-way blind study is written in some parts of the word one-way blind

Acronym

IRCT registration information
IRCT registration number: **IRCT20200114046128N1**
Registration date: **2020-03-15, 1398/12/25**
Registration timing: **retrospective**

Last update: **2020-07-19, 1399/04/29**
Update count: **1**

Registration date
2020-03-15, 1398/12/25

Registrant information

Name
Reza Mohtasham

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
2018-10-07, 1397/07/15

Actual recruitment end date

2019-09-02, 1398/06/11

Trial completion date

2019-09-21, 1398/06/30

Scientific title

A randomized, double-blind controlled trial study comparing the efficacy of granisetron versus lidocaine injection of trigger points in upper trapezius of patients with Myofascial Pain Syndrome referring to the AJA University Hospital

Public title

A randomized, double-blind controlled trial study comparing the efficacy of granisetron versus lidocaine injection of trigger points in upper trapezius of patients with Myofascial Pain Syndrome referring to the AJA University Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being at least 18 years old Neck or shoulder pain complaints for at least one month At least one trigger point in the upper trapezius muscle Non pregnant woman No prior disease (severe cystic, spine, spinal canal stenosis) No history of fibromyalgia or rheumatic diseases No prior history of allergy to Granisetron or lidocaine

Exclusion criteria:

No patient co-operation No refer for follow up Pain aggravation (unbearable for patient)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocating of two groups with the same size of 20 participants (40 patients in total) we used block randomization with different block sizes. The sizes of blocks would be a multiple of 2 and a divisor of 40 (2,4,8). At first, the block sizes were selected randomly. Then, for each block, different permutations for equal group size were determined. Finally, one of the permutations was selected randomly. Random numbers were generated in an independent statistical office and with the help of a computer.

Blinding (investigator's opinion)

Double blinded

Blinding description

Our study was a double-blind randomized trial. The participants, investigators, and clinicians were unaware of the treatment assignments. The sequence of allocation was concealed from all investigators and participants with sequentially numbered sealed envelopes prepared at the statistical office. The envelopes contained cards with the group assignments type. A nurse who was neither involved in the intervention nor in the assessments opened the envelope and prepared the solutions for injection based on the treatment assignments. The solution was then injected by a physician blinded to its content. All follow-up evaluations were done by a physical therapist blinded to the group assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Artesh University of Medical Scinces

Street address

501 Hospital, Etemadzade Ave, West Fatemi Blvd

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2019-12-23, 1398/10/02

Ethics committee reference number

IR.AJAUMS.REC.1398.202

Health conditions studied

1

Description of health condition studied

neck and upper trapezius pain

ICD-10 code

M79.1

ICD-10 code description

Myalgia

Primary outcomes

1

Description
Severity of neck pain with Visual Analogue Scale
Timepoint
pain severity at start, one month and 3 months later
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
NDI
Timepoint
Neck disability index at start, one month and 3 months later
Method of measurement
Neck Disability Index

2

Description
NPDS
Timepoint
Neck pain and disability scale at start, one month and 3 months later
Method of measurement
Neck Pain and Disability Scale

Intervention groups

1

Description
Intervention group: patients with complain of Neck pain or Shoulder pain and clinical diagnosis of Myofascial Pain Syndrome in Upper trapezius muscle, single dose 1CC Granisetron (produced by Caspian Co.) were injected
Category
Treatment - Drugs

2

Description
Intervention group: patients with complain of Neck pain or Shoulder pain and clinical diagnosis of Myofascial Pain Syndrome in Upper trapezius muscle, single dose 1CC Lidocaine 0.5% (produced by Caspian Co.) were injected
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
501 Hospital
Full name of responsible person
Sharif Najafi
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
ندارد
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Aja university
Proportion provided by this source
1
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person

Reza Mohtasham

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Medical Education

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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