

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of the effectiveness of early intra-shoulder injection with receiving only physiotherapy treatment in patients with chronic shoulder pain referred to the orthopedic clinic of Imam Khomeini and Golestan educational centers in Ahvaz

Protocol summary

Study aim

Comparison of the effectiveness of early intra-shoulder injection with receiving only physiotherapy treatment in patients with chronic shoulder pain referred to the orthopedic clinic of Imam Khomeini and Golestan educational centers in Ahvaz in 1400

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

the research is done in golestan and emam khomeini clinical hospital; all diagnosis and examination done in this place. patient dose not know they belong to which group. examiner dose not know which group that he exam.

Participants/Inclusion and exclusion criteria

pain duration more than 6 month; no teruma; no surgery; no injection; patient satisfaction; no neurological disease; no shoulder anomaly

Intervention groups

in first group shoulder injection done in moment of diagnosis; in control group patient goes to physiotherapy without injection

Main outcome variables

treatment; severity of pain; constant score; DASH score; ROM; patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220221054084N1**

Registration date: **2022-03-26, 1401/01/06**

Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**

Update count: **0**

Registration date

2022-03-26, 1401/01/06

Registrant information

Name

Payam Mohammad hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3392 4050

Email address

mohammadhoseini-p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of early intra-shoulder injection with receiving only physiotherapy treatment in patients with chronic shoulder pain referred to the orthopedic clinic of Imam Khomeini and Golestan educational centers in Ahvaz

Public title

evaluation of early shoulder injection in chronic shoulder pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

duration of pain more than 6 month no history of trauma
no history of shoulder surgery no history of shoulder
injection patient wants to be participated

Exclusion criteria:

age below 18 or more than 65 history of treatment like
our treatment present of systemic inflammatory disease
neurological condition involved upper extremity allergic
reaction or contraindication for corticosteroid anatomical
abnormality in shoulder x ray if the patient does not
want to be participate

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients are done with computerized
software random allocation software that divides patients into
two groups by using blocking system, for example every 8
patients belong to each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Physiotherapist does not know about which patient belongs to
which group practitioner does not know that the patient
belongs to which group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz Golestan Hospital

Street address

No. 3; west 17th street; Kian Pars Blvd

City

Ahwaz

Province

Khuzestan

Postal code

6155883464

Approval date

2022-02-13, 1400/11/24

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.170

Health conditions studied

1

Description of health condition studied

chronic shoulder pain after adhesive capsulitis;
impingement syndrome; sub acromial bursitis; shoulder
dysjoints.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

severity of shoulder pain

Timepoint

at time of diagnosis; 6 weeks after initial treatment; 12
weeks after initial treatment

Method of measurement

visual analogue score

Secondary outcomes

empty

Intervention groups

1

Description

Control group: under 16 section of shoulder
physiotherapy that includes same physiotherapist same
devices an order is exercise isometrics and emphasizing on
aggressive range of motion.

Category

Rehabilitation

2

Description

Intervention group: under 80 ml intra shoulder injection
methylprednisolone from Exir Co with 5 cc of NaCl; 15 section
of shoulder physiotherapy same as another group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

emam khomeini hospital

Full name of responsible person

payam mohammadhoseini

Street address

No.3 , west 17th street, kian pars Blvd

City

ahwaz

Province

Khouzestan

Postal code

6155883464

Phone

+98 61 3337 6686

Email

Mohammadhoseini-p@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

mohamad mohamadi

Street address

No 3, west 17th st, kian pars Blvd

City

ahwaz

Province

Khouzestan

Postal code

6155883464

Phone

+98 61 3337 6686

Email

Mohammadhoseini-p@ajims.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

ahwaz university of medical sciens

Proportion provided by this source

1

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

Ahvaz University of Medical Sciences

Full name of responsible person

payam mohammadhoseini

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all of data that used in this research

When the data will become available and for how long

one year after publish

To whom data/document is available

for academic practitioner

Under which criteria data/document could be used

use for systemic reveiw research

From where data/document is obtainable

Mohammadhoseini-p@ajums.ac.ir

What processes are involved for a request to access data/document

2 weeks

Comments