

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The Effects of Arthrocentesis on Signs and Symptoms in Acute and Severe Limited Mouth Opening

Protocol summary

Summary

This is a not-randomized; not-blinded, single clinical trial; which aims to evaluate the effects of Arthrocentesis of patients with limited mouth opening and reduction of pain and dysfunction. Fifteen referred patients suffering from limited mouth opening, pain and dysfunction are first diagnosed by clinical examination and radiography after signing consent form; arthrocentesis is performed. Mouth opening is measured by the researcher with a ruler in millimeter. Patients define level of their pain and dysfunction on separated visual analog scales (VAS) which are scaled 0 to 10. Arthrocentesis is performed in clinic, under local anesthesia, two low gauge needles are inserted into upper temporomandibular joint compartment and lavage is done by 200 milliliters of Ringer's lactated solution. After arthrocentesis patients are visited in 1, 3 and 6 months follow-ups, in these visits mouth opening, level of pain and dysfunction are measured the way as described prior.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040721636N1**
Registration date: **2015-11-04, 1394/08/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-04, 1394/08/13

Registrant information

Name

Safa Motevasselée

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Arthrocentesis on Signs and Symptoms in Acute and Severe Limited Mouth Opening

Public title

The Effects of Arthrocentesis on Acute Limited Mouth Opening

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with acute and severe limited mouth opening suffering from pain and dysfunction and not responded to non-surgical treatments. Exclusion criteria: patients with symptoms such as condylar fracture; systemic joint or muscle disease and major jaw deformity; fibrous adhesion are excluded from the study.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Science

Street address

Iran radiator building, west Shahid Beleshti blv, Gaz square

City

Rasht

Postal code

9334541938

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.GUMS.REC.1394.174

Health conditions studied

1

Description of health condition studied

internal derangements of temporomandibular joint

ICD-10 code

K07.6

ICD-10 code description

certain disorders of the temporomandibular joint

Primary outcomes

1

Description

mouth opening

Timepoint

Once before arthrocentesis and 1month after the intervention; 3months after the intervention ;and 6 after the intervention

Method of measurement

Mouth opening; lateral motions to right and left and also protusive movements are measured by researcher with a ruler in millimeter.

2

Description

pain

Timepoint

Once before arthrocentesis and 1month after the intervention; 3months after the intervention ;and 6 month after the interventions

Method of measurement

Patients define their level of pain on rulers scaled from 0(no pain)to 10(intolerable pain).

3

Description

dysfunction

Timepoint

Once before arthrocentesis and 1month after the intervention; 3months after the intervention ;and 6 months after the intervention

Method of measurement

Patients define their level of dysfunction on rulers scaled from 0(ideal function)to 10(lack of function).

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Procedure starts by injection of a local anesthetic;Lidocaine 2% with Epinephrine 1/100000 to block the nerve;this is followed by arthrocentesis. Post operative medication consisted of Naproxen sodium 275 mg three times daily and diazepam 2.5 to 5 mg/d before bedtime to be taken for two weeks.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Pour-sina hospital

Full name of responsible person

Dr.Safa Motevasselee

Street address

Pour-sina hospital,Pour-sina crossroad,Hafez Ave.

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Susan Komaie

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Opposite Sepah band, West Shahid Beheshti Blv. Gaz Square

City

Rasht

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research of Guilan University of Medical Sciences

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**

Guilan University of Medical Sciences

Full name of responsible person

Hedieh Dowlatshahizand

Position

dentistry student

Other areas of specialty/work**Street address**

Guilan University of Medical Sciences Complex Buildings, Faculty of Dentistry, Saravan Free way, Lakan Road

City

Rasht

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Faculty of Dentistry, Guilan University of Medical Sciences

Full name of responsible person

Dr.Safa Motevasselee

Position

Assistant professor of oral and maxillofacial surgery

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Guilan University of Medical Sciences, School of dentistry

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Assistant Professor of oral and maxillofacial surgery

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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