Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Motevesselee
Name of organization / entity
guilan university of medical science
Country
Iran (Islamic Republic of)
Phone
+98 13 3348 6411
Email address
drsmotevasselee@gums.ac.ir

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 openig; lateral motions to right and left and also protusive movements are measured by researcher with a ruler in milimeter.

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.
City
Rasht

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
Street address
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
Postal code
4194173774
Phone
+98 21 2292 5125
Fax
Email
hedieh_dz2008@yahoo.com
Web page address

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
Other areas of specialty/work
Street address
Guilan University of Medical Sciences Complex Buildings, Saravan Free way, Lakan road
City
Rasht
Postal code
4194173774
Phone
+98 13 3348 6411
Fax
+98 131323776
Email
drsmotevasselee@gums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Guilan University of Medical Sciences, School of dentistry
Full name of responsible person
Dr.Safa Motevasselee
Position
Assistant Professor of oral and maxillofacial surgery
Other areas of specialty/work
Street address
Guilan University of Medical Sciences Complex Buildings, Saravan Free way, Lakan road
City
Rasht
Postal code
4194173774
Phone
+98 13 3348 6411
Fax
Email
drsmotevasselee@gums.ac.ir
Web page address

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