

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Therapeutic effects of Prolotherapy with intraarticular injection of dextrose solution in patients with moderate knee osteoarthritis-a preliminary intrventional pilot study

Protocol summary

Summary

The purpose of this study is to evaluate the therapeutic effects of prolotherapy with intraarticular injection of dextrose solution in patients with moderate knee osteoarthritis. This is a preliminary interventional pilot study. Study population is 20 patients. We will recruit twenty patients who have our inclusion criteria and don't have our exclusion criteria. At first, patients with osteoarthritis are evaluated with WOMAC questionnaire, which is a valid questionnaire for osteoarthritis and knee range of motion is determined with goniometer. Also, patients demonstrate their level of pain intensity with VAS. When a patient has our inclusion criteria in both knees, just one knee is evaluated by our study. For each patient, 3 intraarticular injections in the manner of time 0, time 1, time 2 will be done. Each injected solution content is composed of 7 c.c dextrose (20%) plus 2 c.c Lidocaine (1%) and will be injected with inferomedial approach. At the end of month one, two, three and six from time 0, injection patients will go under evaluation with WOMAC, they demonstrate their VAS grade again and also range of motion will be detected with goniometer. It is said VAS determination will be in two positions: at rest and after walking for six meters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210213217N4**

Registration date: **2012-10-24, 1391/08/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-10-24, 1391/08/03

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Chancellor of Tabriz University of Medical Science - Physical Medicine and rehabilitation researches center

Expected recruitment start date

2012-10-26, 1391/08/05

Expected recruitment end date

2013-04-26, 1392/02/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of Prolotherapy with intraarticular injection of dextrose solution in patients with moderate knee osteoarthritis-a preliminary interventional pilot study

Public title

Therapeutic effects of Prolotherapy in patients with moderate knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

1- Moderate knee osteoarthritis (grade 2 or 3 based on knee radiographic classification of Kellgren and Lawrence) 2-No history of inflammatory Rheumatologic disease such as RA 3-Patient in the range of 45-75 years old 4-No reception of systemic or IV corticosteroid in two weeks before treatment and along treatment 5-Satisfactory of patients involved in study 6- NO response to conservative and physiotherapeutic treatments during 3 past month

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

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

Research chancellor of Tabriz University of Medical Science

Street address

3rd floor- Central Building Number 2 - Tabriz University of Medical Sciences- Golgasht Avenue

City

Tabriz

Postal code

51656

Approval date

2012-04-16, 1391/01/28

Ethics committee reference number

2060/4/5

Health conditions studied

1

Description of health condition studied

Primary gonarthrosis, bilateral

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes

1

Description

Intensity of pain

Timepoint

Before intervention and one month , two month ,three month and six month after intervention

Method of measurement

Using VAS grading score

Secondary outcomes

1

Description

knee range of motion

Timepoint

Before intervention and one month , two month ,three month and six month after intervention

Method of measurement

Using goniometer

2

Description

Daily functional ability

Timepoint

Before intervention and one month , two month ,three month and six month after intervention

Method of measurement

Using WOMAC questionnaire

Intervention groups

1

Description

Intraarticular injection of 7c.c dextrose 20% plus 2% lidocaine 1% with inferomedial approach in each injection time. For each patient three intraarticular injection in the manner of time 0 , time 1 and time 2 will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital of Tabriz
Full name of responsible person
Bahman Amouzandeh
Street address
Daneshgah Ave.
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Physical medicine and rehabilitation researches center
Full name of responsible person
Dr.Salim Vahedi
Street address
Emam Reza hospital - Department of Physical medicine and rehabilitation researches center
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Physical medicine and rehabilitation researches center
Proportion provided by this source
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

2

Sponsor

Name of organization / entity
Research chancellor of Tabriz University of medical sciences
Full name of responsible person
Azam Saafi
Street address
Research chancellor- 3rd floor-central building number 2 -Tabriz university of medical sciences - Golgasht Ave.
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research chancellor of Tabriz University of medical

sciences
Proportion provided by this source
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
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Full name of responsible person
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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