Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of long term efficacy of dextrose prolotherapy with hyalgan in knee Osteoarthritis

Protocol summary

Summary

AfterThe accurate diagnosis of osteoarthritis (clinical and radiographic) , And evaluation of patient inclusion &exclusion criteria for the study, Details of treatment is described and the patient's written consent is obtained.Other drug treatments (NSAID, corticosteroids and other anti-inflammatory drugs) and non pharmacological (knee physiotherapy modalities are included, TENS, laser, etc.) will be discontinued 48 hours before the start of the intervention. Then initial knee x-ray is taken. And according to radiographic criteria, grading is done and initial patient questionnaire is completed.Then knee joint range of motion (ROM) measured by Goniometr &Medial and lateral joint line tenderness is reviewed & Pain intensity on VAS (state separation as the rest, walking, sitting, etc.) And according to the WOMAC questionnaire is assessed. The grouping is done, the other person does the first Hyalgan injections and hypertonic dextrose or 20% .A total of 3 patients were injected into the knee joint to be considered. Injections in patients treated with Hyalgan, at intervals of one week (vials 2 ml prepared hyaluronic acid) and in patients treated Prolotherapy three injections at intervals of one month (compound 9 ml of glucose 20% with 1 cc of lidocaine 2% in a syringe 10 cc) is done. After injection, it is recommended that patients have a relative rest for 48 hours, it increases the duration of maintaining and enhancing the response to treatment. for sterility , sterile gloves & sterile infusion sets are used. Before each injection, patients were reassessed for pain (VAS and a questionnaire based on numerical criteria WOMAC), range of motion, tenderness of the joint line (medial and lateral) and injection complications (infection, Hemartrosis,...) are checked. Patients can be followed during the course of the pain, take acetaminophen 325, But the 12 hours prior to treatment to follow, do not use acetaminophen. After treatment protocol (three injections and in each stage of the assessment), range of motion, pain and joint line tenderness is measured.

General information

Acronym

Comparison of prolotherapy with hyalgan

IRCT registration information

IRCT registration number: **IRCT2013031712831N1**
Registration date: **2013-08-28, 1392/06/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-28, 1392/06/06

Registrant information

Name

Masoumeh Bahrami Asl

Name of organization / entity

Army University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8833 7915

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masoomehbahrami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Army University of Medical Sciences

Expected recruitment start date

2013-06-11, 1392/03/21

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of long term efficacy of dextrose prolotherapy with hyalgan in knee Osteoarthritis

Public title

Comparison of long term efficacy of dextrose prolotherapy with hyalgan in knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 50 years old; cripitation or morning stiffness less than 30 min & radiologic criteria of OA. Exclusion criteria: diabetes mellitus; other joint disease (RA,...); surgery in knee; fx history;recent corticosteroid injection; immunosuppression and massive knee effusion.

Age

From **50 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

army university of medical science

Street address

Imam reza(501) hospital - Etemad Zadeh street- Fatem

City

tehran

Postal code

Approval date

2013-06-11, 1392/03/21

Ethics committee reference number

9204

Health conditions studied

1

Description of health condition studied

knee OA

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain severity (pain score)

Timepoint

1 week, 1 month, 3 month , 8 month and 12 month

Method of measurement

VAS ruller

2

Description

knee joint range of motion

Timepoint

1 week, 1 month, 3 month , 8 month and 12 month

Method of measurement

goniometr

3

Description

quality of life

Timepoint

1 week, 1 month, 3 month and 8 month

Method of measurement

WOMAC questionary

Secondary outcomes

1

Description

infection

Timepoint

1 week, 1 month, 3 month , 8 month and 12 month

Method of measurement

physical exam

Intervention groups

1

Description

intervention:in prolotherapy group we use ,9cc of 20% dextrose + 1cc lidocaine in strill condition & in knee joint space

Category

Treatment - Drugs

2

Description
control: we use prepared vial of 2 cc hyalgan in strill condition & in knee joint space
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital (501)
Full name of responsible person
Dr. Masoumeh Bahrami Asl
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Army 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
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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