

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of Gliseryl trinitrate (GTN) in the treatment of localized Tennis elbow

Protocol summary

Study aim

this study was aimed to evaluate the effectiveness of topical GTN in the treatment of patients with Tennis elbow

Design

Clinical trials with control group, tennis elbow, with parallel groups, blind, randomized

Settings and conduct

In this double-blind clinical trial, a total of 84 patients with Tennis Elbow who referred to orthopedic and rheumatology clinics of Bou-Ali Hospital in the control and control groups were 45 and 39, respectively. These patients were included in the study, which was presented to patients with skin patches containing glyceryl nitrate or liquid paraffin (placebo) at the start of the study and recommended that patients receive 20 drops per day at the place where the most tenderness The elbows are localized and can be used on patches for 12 hours during the day. In this study, 4 groups of patients, clinical caregivers, outcome evaluators, and data analyzers were kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 16 years of age;Patients who have had symptoms for less than 3 months.
Exclusion criteria: Patients with heart disease who have a history of using TNG;People with a history of fracture or dislocation of the joint of the elbow, or a wrist or ligament on these joints;People who have had a history of corticosteroid injections in the last three months;People with distal neurological signs to the elbow. People with seronegative enteropathy

Intervention groups

At the start of the study, patients with dermatological patches and drop containing GTN or liquid paraffin were delivered and patients receive 20 drops daily in the place where the elbow tends to have the highest tendency, and during the period Use patches 12 hours a day, then change the patches the next day and repeat the procedure according to the instructions.

Main outcome variables

Tenderness; Pain severity

General information

Reason for update

Acronym

GTN

IRCT registration information

IRCT registration number: **IRCT20180421039375N3**

Registration date: **2018-12-12, 1397/09/21**

Registration timing: **retrospective**

Last update: **2018-12-12, 1397/09/21**

Update count: **0**

Registration date

2018-12-12, 1397/09/21

Registrant information

Name

Hamid Zaferani Arani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-10-01, 1391/07/10

Expected recruitment end date

2014-01-10, 1392/10/20

Actual recruitment start date

2012-10-02, 1391/07/11

Actual recruitment end date

2014-01-05, 1392/10/15

Trial completion date
2014-01-05, 1392/10/15

Scientific title
A comparative study of Gliseryl trinitrate (GTN) in the treatment of localized Tennis elbow

Public title
Effect of Gliseryl trinitrate (GTN) in the treatment of localized Tennis elbow

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 16 years of age with Tennis Elbow Patients who have symptoms for less than 3 months
Exclusion criteria:
Patients with heart disease who have a history of TNG use People with a history of fracture or dislocation of the joint of the elbow, or a wrist or ligament on these joints People who have had a history of corticosteroid injection over the past three months People who have distal neuronal symptoms to the elbow People with Seronegative enteropathy

Age
From **16 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 84 patients with TE were selected from among the patients referred to the orthopedic and rheumatology clinics of Bou Ali Hospital in a randomized way. They were divided into two groups of case and control. In order to collect the data, eligible patients referred to orthopedic and rheumatology clinics of Bou-Ali Hospital who were willing to participate in the study were randomizedly and blinded by the secretary to two groups receiving drop containing glyceryl nitrate (in the treatment group) And liquid paraffin (placebo in the control group). As these medications were given in two packages (package A, package B) and divided into 2 groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, four groups of Participant, Care provider, Outcome assessor, and data analysers were kept blind. None of these names knew which dishes contained

contained drop glyceryl nitrate or liquid paraffin.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Islamic Azad University of Medical Sciences, Tehran, Iran
Street address
Tehran Medical Branch, Islamic Azad University, Khaghani st, Shari'ati Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19395/1495

Approval date
2012-10-13, 1391/07/22

Ethics committee reference number
13610101912015

Health conditions studied

1

Description of health condition studied
Tennis Elbow

ICD-10 code
M77.1

ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
Pain and tenderness in patients with tennis elbow

Timepoint
Before the intervention and week 2, 4, 6 after intervention

Method of measurement
questionnaire

Secondary outcomes

1

Description

Quality of life Score

Timepoint
Before the start of the study and 2 months after the start of the study

Method of measurement
questionnaire

Intervention groups

1

Description

Intervention group: Glyceryl nitrate recipient group: Delivered to patients with patches of skin and drop containing glyceryl nitrate, and it is recommended that patients receive 20 drop drops per day in the place where the elbow has the highest tenderness, and within 12 hours in Use patches throughout the day in a position, then change the patches the next day and repeat the procedure according to the instructions. Patients were advised to use a wound extensor tendon rehabilitation program that includes 2 seconds of contraction, 10 seconds of rest and 10 seconds of elongation of the muscles for at least 3 treatments per day. Patient follow-up was performed 2, 4, and 6 weeks after the first visit in subsequent visits, and patients were assessed for pain during nocturnal rest and during daily activities, Mandsley test (presence or absence of pain during resistance to Doris flexion of the wrists and pronation of the forearm), epicondylar tenderness in the first visit and pain and tenderness of epicondylar in subsequent visits were evaluated and the relevant results were recorded in the questionnaires.

Category

Treatment - Drugs

2

Description

Control group: The placebo recipient group: Delivered to patients with patches of skin and drop containing liquid paraffin, and it is recommended that patients receive 20 drop drops per day in the place where the elbow has the highest tenderness, and within 12 hours in Use patches throughout the day in a position, then change the patches the next day and repeat the procedure according to the instructions. Patients were advised to use a wound extensor tendon rehabilitation program that includes 2 seconds of contraction, 10 seconds of rest and 10 seconds of elongation of the muscles for at least 3 treatments per day. Patient follow-up was performed 2, 4, and 6 weeks after the first visit in subsequent visits, and patients were assessed for pain during nocturnal rest and during daily activities, Mandsley test (presence or absence of pain during resistance to Doris flexion of the wrists and pronation of the forearm), epicondylar tenderness in the first visit and pain and tenderness of epicondylar in subsequent visits were evaluated and the relevant results were recorded in the questionnaires.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bou-Ali hospital

Full name of responsible person

Shahla Abolghasemi

Street address

Imam Hossein Square - Damavand Avenue - Buali Hospital

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Web page address

<http://bouali-hospital.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Farshad Hashemian

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Tehran University of Medical Sciences, Khaghani St., Shariati St

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Grant name

Grant code / Reference number

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

No

Title of funding source

researcher

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

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

Islamic Azad University

Full name of responsible person

Dr. Shahla Abolghasemi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Latest degree

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Other areas of specialty/work

Others

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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 data can be shared after unidentifiable people. The effect of topical glyceryl trisitrate on the treatment of tennis elbows is shared.

When the data will become available and for how long

After publishing the manuscript in a for 1 year later

To whom data/document is available

All researchers - have no limits

Under which criteria data/document could be used

Provided that the researcher wants to do the same

From where data/document is obtainable

Person responsible for research

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

Email to Person responsible - Checked by the responsible
- Providing information

Comments