Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Topical Trinitrate Glyceryl (TNG) in the Treatment of Tennis Elbow

Protocol summary

Summary

Study aims:The efficacy of topical therapy Tennis elbow Glysryl trinitrate compared with placebo in patients with tennis elbow.Inclusion criteria:Tennis Elbow patients; aged over 16 years to less than 3 months before the start of the trial; the symptoms have been involved. Study population: Patients with Tennis Elbow referred to orthopedic and rheumatology Ali Hospital in Tehran. Sample size: 84 patients in the two treatment groups GTN and control (placebo). Intervention under study and its time length: At baseline, dermal patches and TNG drops (treatment group) or liquid paraffin drops (placebo) were given to the patients and they were instructed to drip 20 drops daily on the site with the greatest local pain of the elbow, and cover it with a patch for 12 hours during the day. They also were trained to change the patch and repeat the instructions the next day and both groups were treated for 6 weeks. Primary outcome measure: The patients were evaluated in terms of pain during rest at night and daily activities as well as Maudsley's test (presence or absence of pain during resistance against bending of wrist extensors and forearm pronation) and in terms of tenderness and pain at epicondyle.

General information

Acronym
TE

IRCT registration information
IRCT registration number: **IRCT2015021421075N1**
Registration date: **2015-07-19, 1394/04/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2015-07-19, 1394/04/28

Registrant information

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Islamic Azad University Tehran Medical Branch

Expected recruitment start date
2013-03-22, 1392/01/02

Expected recruitment end date
2014-03-22, 1393/01/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Topical Trinitrate Glyceryl (TNG) in the Treatment of Tennis Elbow

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

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:Tennis Elbow patients; aged over 16 years to less than 3 months before the start of the trial; the symptoms have been involved. Exclusion

criteria:Patients with heart disease who had a history of GTN; history of fracture or dislocation of the elbow or wrist; or those on the joints had surgery; who had a history of local injection of steroids in the past three months; those with neurological symptoms distal (nerve signals from the reference point) to the elbow; and those who were seronegative patients with enteropathy.

Age
From **16 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University Tehran Medical Branch

Street address
Tehran Medical Branch, Islamic Azad University, khaghani st, shariati Ave, Tehran, Iran

City
Tehran

Postal code
193951495

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
2527

Health conditions studied

1

Description of health condition studied
Tennis Elbow

ICD-10 code
M77.1

ICD-10 code description
Tennis Elbow

Primary outcomes

1

Description
In terms of pain during rest at night and daily activities as well as Maudsley’s test

Timepoint
Before treatment, 2, 4 and 6 weeks after treatment

Method of measurement
Doctor questionnaire and relevant

2

Description
In terms of tenderness at epicondyle

Timepoint
Before treatment, 2, 4 and 6 weeks after treatment

Method of measurement
With doctor visits and questionnaires

3

Description
In terms of pain at epicondyle

Timepoint
Before treatment, 2, 4 and 6 weeks after treatment

Method of measurement
With doctor visits and questionnaires

Secondary outcomes

1

Description
mild to moderate headache

Timepoint
Every six hours

Method of measurement
Diagnosis of the patient's pain

Intervention groups

1

Description
Treatment group:At baseline, dermal patches and TNG drops were given to the patients and they were instructed to drip 20 drops daily on the site with the greatest local pain of the elbow, and cover it with a patch for 12 hours during the day. They also were trained to change the patch and repeat the instructions the next day. This practice continued for 6 weeks.

Category
Treatment - Drugs

2

Description
Control Group:At baseline, dermal patches and liquid

paraffin drops were given to the patients and they were instructed to drip 20 drops daily on the site with the greatest local pain of the elbow, and cover it with a patch for 12 hours during the day. They also were trained to change the patch and repeat the instructions the next day. This practice continued for 6 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu-Ali Hospital

Full name of responsible person
Shahla Abolghasemi

Street address
Boali Hospital, Damavand St, Imam Husein Sq., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Islamic Azad University Tehran Medical Branch

Full name of responsible person
Majid Naghipour

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Islamic Azad University Tehran Medical branch, Khaghani St., Shariati St.

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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
Vice chancellor for research, Islamic Azad University Tehran Medical Branch

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
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Full name of responsible person
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Position
Department of Rheumatology

Other areas of specialty/work

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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