

# 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 Glyceryl 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

##### Name

Shahla Abolghasemi

##### Name of organization / entity

Islamic Azad University Tehran Medical Branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3316 9412

##### Email address

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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

**City**

Tehran

**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

**Street address**

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

**City**

Tehran

**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**

Islamic Azad University Tehran Medical Branch

**Full name of responsible person**

Dr Shahla Abolghasemi

**Position**

Department of Rheumatology

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**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*