

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of Tramadol/paracetamol versus placebo as an analgesic in patients undergoing Electromyography study

#### Protocol summary

##### Summary

Objectives and Design: This study is a cross over double blind placebo controlled trial to evaluate the analgesic effects of Tramadol/Paracetamol in healthy volunteers undergoing electromyography procedure. Setting and conduct: Prior to EMG study 2 tramadol/paracetamol or placebo tablets are given to each subject and then the EMG study will be done in 4 muscle areas (first dorsal interosseous, Biceps, Vastus lateralis and Tibialis Anterior) of each subject (half side in each session) and pain scale is evaluated immediately after the procedure and over the next 2 hours using VAS (visual analogue scale) pain scale scoring system. Next session is arranged 2 weeks later which VAS pain scoring is done with the mentioned fashion above on the opposite body side of participants. In this session Tramadol/Paracetamol group receives placebo and vice-versa. Participants: Ninety subjects aged between 18-50 years will be recruited. Exclusion criteria includes: Epilepsy; Opioid hypersensitivity; Diabetes; Liver or Kidney dysfunction; Severe respiratory disease(asthma or Chronic Obstructive Pulmonary Disease); Opioid use or abuse; Selective Serotonin Reuptake Inhibitors or MAO inhibitor or analgesic use; Tricyclic Antidepressants or Neuroleptic use. Intervention: Electromyography and Tramadol/paracetamol tablet. Main outcome measures: Main outcome measures includes Visual Analogue Scale for pain scoring. data will be analyzed using SPSS program.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012111011424N1**

Registration date: **2013-04-24, 1392/02/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-04-24, 1392/02/04

##### Registrant information

###### Name

Abbas Tafakhori

###### Name of organization / entity

Iranian Center of Neurological Research

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6691 0491

###### Email address

a\_tafakhori@sina.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, ,Tehran University of Medical Sciences

##### Expected recruitment start date

2013-04-21, 1392/02/01

##### Expected recruitment end date

2013-08-23, 1392/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Tramadol/paracetamol versus placebo as an analgesic in patients undergoing Electromyography study

##### Public title

Evaluation of Tramadol/Paracetamol versus placebo in reducing pain of Electromyography study

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria includes: normal subject aged between 18-50 years. Exclusion criteria includes: Epilepsy; Opioid hypersensitivity; Diabetes; Liver or Kidney dysfunction; Severe respiratory disease(asthma or Chronic Obstructive Pulmonary Disease); Opioid use or abuse; Selective Serotonin Reuptake Inhibitors or MAO inhibitor or analgesic use; Tricyclic Antidepressants or Neuroleptic use.

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences Ethics Committee

**Street address**

Qods Avenue, Tehran

**City**

Tehran

**Postal code**

1419733141

**Approval date**

2012-09-01, 1391/06/11

**Ethics committee reference number**

130/1176/91/3

**Health conditions studied****1****Description of health condition studied**

pain

**ICD-10 code**

M79.6

**ICD-10 code description**

pain in limb

**Primary outcomes****1****Description**

Visual Analog Scale (VAS) score

**Timepoint**

after and 2 hours after EMG

**Method of measurement**

estimation of pain severity on 100 scale

**Secondary outcomes****1****Description**

side effects

**Timepoint**

after and 2 hours after drug consumption

**Method of measurement**

asking patient

**Intervention groups****1****Description**

two Tramadol/paracetamol(37.5/325 mg) tablets 2 hours before EMG study is done in every session.

**Category**

Treatment - Drugs

**2****Description**

two placebo tablets 2 hours before EMG study is done in every session.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Iranian Center of Neurological research, Imam Khomeini Hospital Complex

**Full name of responsible person**

Dr. Abbas Tafakhori

**Street address**

Keshavarz boulevard, Imam Khomeini hospital, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotuhi

**Street address**

Tehran university of Medical sciences building, Qods avenue, Keshavarz boulevard, Tehran

**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, Tehran 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****Name of organization / entity**

Tehran University of Medical sciences

**Full name of responsible person**

Abbas Tafakhori

**Position**

assistant professor of neurology

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*