

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 dosal interoseous, 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

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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