

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluate the safety and efficacy of oral Tramadol in patients undergoing colonoscopy

Protocol summary

Summary

This study was designed to evaluate the safety and efficacy of oral tramadol in patients undergoing colonoscopy. A total of 90 patients scheduled for colonoscopy referred to Mahdiah clinic of Kermanshah University of Medical Sciences, After obtaining informed consent, Randomly divided into two groups: Recipient of a tablet 100mg of tramadol, 4 hour before colonoscopy and The control group did not receive tramadol, they only receive a multivitamin. The patients undergoing colonoscopy. Blinding was done for the patient and the person performing the colonoscopy. Measurable outcomes about Safety and efficacy include physician satisfaction, Sweating and restlessness, Muscle movements, The sound produced by the patient, recovery duration, Discharge, Nausea and vomiting that Recorded for each patient. By application of statistical analysis, comparisons between the two groups was done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010820610N1**
Registration date: **2015-02-22, 1393/12/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-22, 1393/12/03

Registrant information

Name

Teymor Kamari

Name of organization / entity

Kermanshah University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the safety and efficacy of oral Tramadol in patients undergoing colonoscopy

Public title

Evaluate the safety and efficacy of oral Tramadol in patients undergoing colonoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20 to 65 years, for whatever reason are candidates for colonoscopy.

Exclusion criteria: People who have a history of drug abuse, People who have drug allergies, Heart disease, Or chronic systemic diseases.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

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

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of
Medical Sciences

Street address

Shahid Beheshti.Blv,

City

Kermanshah

Postal code

Approval date

2014-09-02, 1393/06/11

Ethics committee reference number

23311

Health conditions studied

1

Description of health condition studied

Diseases of the digestive system

ICD-10 code

K90-K93

ICD-10 code description

Other diseases of the digestive system

Primary outcomes

1

Description

pain density

Timepoint

During colonoscopy

Method of measurement

Visual Analogue Scale for pain

Secondary outcomes

1

Description

Safety and efficacy of oral tramadol on pain

Timepoint

During colonoscopy

Method of measurement

Visual Analogue Scale for pain

Intervention groups

1

Description

Intervention: oral Tramadol One pill of oral Tramadol , 4
hours before colonoscopy

Category

Treatment - Drugs

2

Description

Control group: Multivitamin One pill of oral Multivitamin ,
4 hours before colonoscopy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh clinic

Full name of responsible person

Teymor kamari

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Kermanshah
University Of Medical Sciences

Full name of responsible person

Korosh Hamzehee

Street address

Shahid Beheshti Blv, Kermanshah

City

Kermanshah

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 of Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Teymor kamari

Position

Resident of internal medicine

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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