Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 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 Mahdieh clinic of Kermanshah University of Medical Sciences , After obtaining informed consent, Randomly divided into two groups:Recipient of a tablet 100mg of teramadol, 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

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Name of organization / entity
Kermanshah University of Medical Science
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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
Koroush 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
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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