Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

celecoxib in the treatment of mild to moderate depression in patients with colon cancer: A randomized placebo controlled trial

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of celecoxib in the treatment of mild to moderate among patients with colon cancer receiving chemotherapy in a six-week double-blind, placebo controlled trial. 40 adult outpatients who meet the DSM-5 criteria for major depression(mild to moderate) will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score below 20 will be randomly allocated into two groups. 20 persons will receive celecoxib 200 mg BID and 20 participants will receive placebo. Patients were assessed by a psychiatrist at baseline and after 2,4 and 6 weeks after the medication started. Efficacy will be defined as the change from baseline to endpoint in score on Hamilton Rating Scale for Depression. Severity of pain will be assessed by Visual Analogue Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508201556N79**
Registration date: **2015-08-23, 1394/06/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-23, 1394/06/01

Registrant information

Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 5541 2222
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

celecoxib in the treatment of mild to moderate depression in patients with colon cancer: A randomized placebo controlled trial

Public title

Antidepressant effects of Celecoxib in the treatment of patients with colon cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Confirmation of colon cancer;2-receiving chemotherapy 3- score lower than 20 in Hamilton Rating Scale for depression 4-Mild to moderate major depressive disorder based on DSM-5 Exclusin criteria: 1-psychosis or other psychiatric disorder 2-Receiving psychotropic medications,3- receiving any antidepressants during past one month or ECT during past two months 4-history of cardiovascular disease , 5-pregnancy or breast feeding, 6-thyroid diseases

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
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 Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Keshvarz Blvd
City
Tehran
Postal code
Approval date
2015-08-06, 1394/05/15
Ethics committee reference number
IR.TUMS.REC.1394.568

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder
ICD-10 code
F32
ICD-10 code description
Major Depressive episode

Primary outcomes

1

Description
Severity of depression
Timepoint
Baseline and weeks 2-4-6 after beginig of treatment
Method of measurement
by Hamiltion Depression Rating Scale 17-Item

Secondary outcomes

1

Description
severity of pain
Timepoint
Baseline and weeks 2-4-6 after beginig of treatment
Method of measurement
by Visual Analogue Scale

Intervention groups

1

Description
Capsule Celecoxib200 mg BID as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Cap. placebo as control group for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Prof. Shahin Akhondzadeh
Street address
South Kregar street, Roozbeh
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Masoud Yunesian
Street address
Tehran University of Medical Sciences, Keshvarz Blvd
City
Tehran
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Prof. Shahin Akhondzadeh
Position
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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