

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

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 Exclusion 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 Hamilton 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

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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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