

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Efficacy of adjunctive Celecoxib in improvement of Obsessive-compulsive disorder

Protocol summary

Summary

The objective of this study was to assess Efficacy of adjunctive Celecoxib in improvement of Obsessive-compulsive disorder This study is a double blind case - control study in a large referral psychiatric university hospital in Iran (Mashhad) from June 2014 to September 2015 Inclusion criteria: patients were met DSM IV criteria for diagnosis of OCD by a psychiatrist based on structured interview exclusion criteria: they met criteria for bipolar I or bipolar II disorder; eating disorders, personality disorders, substance dependence or abuse history of gastrointestinal bleeding, and use of any medications identified as contra-indicated with COX-2 inhibitors all Patients were referred to Ibn Sina clinic visited by resident of psychiatry and after written informed consent they randomized to receive celecoxib or placebo .in case group SSRI plus celecoxib 400 mg/day (200 mg bid) and in placebo group SSRI plus placebo in same shape and dose Patients were assessed with the Y-BOCS and CGI at baseline and 4, 8 and 12 weeks after the start of the treatment. Examinations of the patients during the treatment period was performed by blind psychiatrist trained Hamilton depression and anxiety tests for all patients by a psychiatrist at baseline and after 12 weeks will be done. Patients will be enrolled according to Hamilton test if they don't require medical treatment for anxiety and severe depression All side effects of medications at each visit based on the list prepared by the assistant psychiatry and if necessary tests will be done according to the discretion of the psychiatrist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512235280N21**

Registration date: **2016-01-05, 1394/10/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-05, 1394/10/15

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Mashhad University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of adjunctive Celecoxib in improvement of Obsessive-compulsive disorder

Public title

Efficacy of adjunctive Celecoxib in improvement of Obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Patients were considered for participation in the project if they were met DSM-1V criteria for diagnosis of OCD. The diagnosis was confirmed by a psychiatrist based on structured interview ; A minimum score of 21 or above on the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS). Exclusion: The patients did not receive any Psychotropic medications such as selective serotonin reuptake inhibitors (SSRIs), tricyclic Antidepressants (TCAs), or monoamine oxidase inhibitors for 4 weeks preceding entry into the trial Patients; they suffered from known autoimmune disease; bipolar I or bipolar II disorder; eating disorders; personality disorders; mental retardation; substance dependence or abuse; had a concurrent medical illness; history of seizures that would contraindicate use of the study medication; receiving ECT; peptic ulcers or a history of gastrointestinal bleeding; use of any medications identified as contraindicated with COX-2 inhibitors.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

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**

Ethical Committee of Mashhad University of Medical sciences

Street address

Ghoraishy Building, University St.

City

Mashhad

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

922796

Health conditions studied**1****Description of health condition studied**

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes**1****Description**

Obsessive-compulsive disorder

Timepoint

baseline, 4, 8, 12 weeks

Method of measurement

Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)

2**Description**

Depression

Timepoint

Baseline,12 th weeks

Method of measurement

Hamilton Depression Rating Scale

3**Description**

Anxiety

Timepoint

Baseline,12 th weeks

Method of measurement

Hamilton Anxiety Rating Scale

4**Description**

Illness severity

Timepoint

Baseline, 1, 2, 3,4 weeks

Method of measurement

Clinical Global Impression (CGI)

Secondary outcomes**1****Description**

Side Effect

Timepoint

baseline, 4, 8, 12 weeks

Method of measurement

Check List

Intervention groups

1

Description

In case group SSRI plus celecoxib 400 mg/day (200 mg bid).

Category

Treatment - Drugs

2

Description

placebo group SSRI plus placebo in same shape and dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn e Sina Hospital

Full name of responsible person

Dr Najmeh Shahini

Street address

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,
Mashhad,Iran.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mashhad University of
Medical Sciences

Full name of responsible person

Dr Mahyar Mirheydari

Street address

Administration Center(Qoreishi Building) – Daneshgah
St. – Mashhad – Iran

City

Mashhad

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 Mashhad 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

Mashhad University of Medical sciences

Full name of responsible person

Dr Najmeh Shahini

Position

Resident

Other areas of specialty/work

Street address

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,
Mashhad,Iran.

City

Mashhad

Postal code

Phone

+98 51 3711 2701

Fax

Email

shahinin921@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical sciences

Full name of responsible person

Dr Najmeh Shahini

Position

Resident

Other areas of specialty/work

Street address

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,
Mashhad,Iran.

City

Mashhad

Postal code

Phone

+98 51 3711 2701

Fax

Email

shahinin921@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Najmeh Shahini

Position

Resident

Other areas of specialty/work**Street address**

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,
Mashhad,Iran.

City

Mashhad

Postal code**Phone**

+98 51 3711 2701

Fax**Email**

shahinin921@mums.ac.ir

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