

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of olanzapine on symptom- relief and quality of life in gastric cancer patients receiving chemotherapy

Protocol summary

Summary

This study is conducted to evaluate the efficacy of olanzapine in symptom-relief and quality of life in gastric cancer patients. Study population is gastric cancer patients referring to cancer- treatment centers affiliated to Babol University of Medical Science, Northern Iran, whose disease is recently diagnosed and are candidate for chemotherapy. Inclusion criteria are diagnosis of gastric cancer in the patient and administration of chemotherapy protocol for the patient by related medical team. The patients with severe psychiatric disorders or receiving other antipsychotic drugs such as risperidone, clozapine, phenothiazine, ... in the last 30 days; the patients with severe neurologic diseases; mental retardation; abnormal laboratory tests in the serum level of creatinine, bilirubin, hepatic enzymes; neutrophil count; pregnancy; uncontrolled cardiac diseases in the last 6 months; and uncontrolled diabetes mellitus will be excluded. 30 eligible patients will be allocated randomly in the case and control groups. The intervention group will receive olanzapine (5-10 milligram per day) from a day before chemotherapy to 8 weeks after chemotherapy, besides the routine treatment which is implemented for the control group. The patients will be followed in 6 days after chemotherapy to assess adverse reactions and patients' tolerance; also the appetite and other physical symptoms will be followed by phone calls and free doctor's visit and medical interview- as necessary-. Finally, the patients will be followed at the 4th and 8th weeks after chemotherapy; treatment response, the status of depression and anxiety in the patients and the quality of life in the two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070822991N2**

Registration date: **2016-02-01, 1394/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Sussan Moudi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 5683

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sussan.mouodi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of olanzapine on symptom- relief and quality of life in gastric cancer patients receiving chemotherapy

Public title

Effect of olanzapine in gastric cancer patients receiving chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: gastric cancer patients whose disease diagnosed recently and candidate for chemotherapy; patient's informed consent for participation in the study
Exclusion criteria: history of severe psychiatric problems such as severe cognitive disorders, psychotic disorders, antipsychotic medication such as risperidone, clozapine, phenothiazine,... in 30 days before or duration of the protocol; history of severe neurologic diseases such as metastasis to the brain, convulsion, ...; mental retardation; serum creatinine level more than 2 milligram per deciliter; total serum bilirubin level more than 2 milligram per deciliter; hepatic enzymes more than three times higher than upper limit of normal range; neutrophil count less than 1500; pregnancy; uncontrolled cardiac diseases such as cardiac arrhythmias, heart failure, acute myocardial infarction in the last 6 months; uncontrolled diabetes mellitus

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooz Avenue, Babol

City

Babol

Postal code

4136747176

Approval date

2013-12-21, 1392/09/30

Ethics committee reference number

3480

Health conditions studied

1

Description of health condition studied

Neoplasms

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

Quality of life

Timepoint

4th and 8th week after initiation of chemotherapy

Method of measurement

with standard questionnaire of WHO- QOL- BREF

2

Description

severity of depression and anxiety in the patient

Timepoint

4th and 8th weeks after chemotherapy

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

Secondary outcomes

1

Description

Nausea and Vomiting

Timepoint

before treatment to six days after chemotherapy

Method of measurement

Rhodes index

Intervention groups

1

Description

Intervention group will receive 5-10 milligram per day olanzapine tablet from one day before chemotherapy to 8 weeks after chemotherapy, besides routine chemotherapy medication.

Category

Treatment - Drugs

2

Description

Control group will receive only routine chemotherapy medication.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated to Babol University of Medical Sciences

Full name of responsible person

Novin Nikbakhsh, MD

Street address

Babol, Shahid Beheshti Hospital, Department of Surgery

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ali Akbar Moghadamnia

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue, Babol

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Grant name

معاونت تحقیقات و فن آوری دانشگاه علوم پزشکی و خدمات بهداشتی درمانی بابل

Grant code / Reference number

2097

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi, MD

Position

Assistant Professor of Psychiatry

Other areas of specialty/work

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Person responsible for updating data

Contact

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