

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and comparison of the effect of haloperidol and quetiapine in the prevention of delirium in patients with end-stage cancer candidates receiving palliative care at home

Protocol summary

Study aim

Determination and comparison of frequency distribution (relative frequency) of delirium incidence in three groups receiving haloperidol, quetiapine and control group

Design

This study uses a double-blind randomized clinical trial with a control group and parallel randomized groups, which examines and compares the effect of haloperidol and quetiapine (manufactured by Iranian companies) in the prevention of delirium in end-stage cancer patients. Excel random rendering software is used for randomization

Settings and conduct

The study sample is selected from patients of Omid Hospital and Isfahan Branch of Ala Cancer Prevention and Control Center (MAXA) in 1399. Individuals are divided into 3 groups by random block method. In this way, the first 3 qualified people are selected and after obtaining consent, they enter to participate in the study. These 3 people are considered as a triple block and are arranged according to the last digit of the national code. Prevention methods are identified as A, B and C, and all three compounds are identified, and after the last administration of drugs for the last block, we decode.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of any type of end-stage cancer in the patient by an oncologist (discontinuation of treatment with a prognosis of less than 6 months) Conscious consent of the patient or his family to participate in the study Exclusion criteria: Existence of major neurocognitive disorder Existence of delirium disorder according to DSM-V criteria by a psychiatric assistant and obtaining a score less than 5 in the ICDSC questionnaire Any contraindications to the use of antipsychotic drugs

Intervention groups

Group A: Haloperidol receptor (1 mg daily / divided into 2

doses) Group B: Quetiapine receptor (25 mg daily / divided into 2 doses)

Main outcome variables

Delirium prevention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201205049612N1**

Registration date: **2021-01-16, 1399/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-16, 1399/10/27**

Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

Mehrshad Kebari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3435 3008

Email address

mehrshad_m19@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of the effect of haloperidol and quetiapine in the prevention of delirium in patients with end-stage cancer candidates receiving palliative care at home

Public title
Comparison of the effect of haloperidol and quetiapine in the prevention of delirium in patients with end-stage cancer candidates receiving palliative care at home

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of any type of end-stage cancer in the patient by the oncologist (discontinuation of therapeutic treatment with a prognosis of less than 6 months)
Conscious consent of the patient or his family to participate in the study
Exclusion criteria:
Existence of major neurocognitive disorder
Existence of delirium disorder according to DSM-V criteria by a psychiatric assistant and obtaining a score less than 5 in the ICDSC questionnaire
Any contraindications to the use of antipsychotic drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are divided into 3 groups by random block method. In this way, the first 3 qualified people are selected and after obtaining consent, they enter to participate in the study. These 3 people are considered as a triple block and are arranged according to the last digit of the national code. Prevention methods are specified as A, B and C, and we identify all three compounds, and after the last prescription of drugs for the last block, we decrypt.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the randomized block method, individuals are divided into three groups and then the drug is prepared by an individual and specified with a code and given to the researcher (student). The researcher starts the

medication and evaluates the patients on a weekly basis using a questionnaire and records the results based on the patient code. Patients are also unaware of the type of medication they are receiving.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-09-28, 1399/07/07

Ethics committee reference number

IR.MUI.MED.REC.1399.542

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

Delirium prevention

Timepoint

12 weeks after starting the drug

Method of measurement

ICDSC questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Haloperidol receptor (1 mg daily / divided into 2 doses)

Category

Treatment - Drugs

2

Description

Intervention group: Quetiapine receptor (25 mg daily / divided into 2 doses)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayed Al-Shuhada Medical Center

Full name of responsible person

Mohammadreza Sharbafchi

Street address

Sayed Al-Shohada Hospital, Nahr Farshadi Alley, Khayyam Street

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2

Recruitment center

Name of recruitment center

Ala Cancer Prevention and Control Center (Mexa)

Full name of responsible person

Mohammadreza Sharbafchi

Street address

No. 29, Amin Al-Dawlah dead end, Alley No. 35, after the intersection of Shiri Bridge, Motahhari St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou Javanmadri

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Sharbafchi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Full name of responsible person

Mohammadreza Sharbafchi

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Esfahan University of Medical Sciences

Full name of responsible person

Mehrza Kebari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable