

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and Comparison of the Effect of Haloperidol, Risperidone, and Quetiapine Medications in the Treatment of Delirium in End-stage Cancer Patients

Protocol summary

Study aim

Determining the Effect of Haloperidol, Risperidone, and Quetiapine in the Treatment of Delirium in End-stage Cancer Patients

Design

This study is a clinical trial with a control group, with parallel groups and randomly controlled double-blind, phase 3 on 60 patients, which examines and compares the effects of haloperidol, quetiapine, and risperidone. The random block method is used for randomization.

Settings and conduct

The study sample is selected from patients of Omid Hospital. Medications are started at the lowest dose and increased daily until the delirium symptoms improve or the dose is reached. The Intensive Care Delirium Screening Checklist is used to assess the response to treatment. This questionnaire is completed daily until recovery and then every 2-7 days after recovery. One person randomizes individuals into three groups and then adjusts the daily dose of the drug until a therapeutic response is achieved. The second person, who has no information about the type of drug used, evaluates patients on a daily basis using a questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of any type of end-stage cancer, informed consent of the patient or family, age over 18 years, diagnosis of delirium based on DSM-V criteria; Exclusion criteria: Existence of major neuromagnetic disorder, prohibition of antipsychotic drugs

Intervention groups

Group 1: Haloperidol Receiver (1-6 mg daily) Group 2: Quetiapine Receiver (25-400mg daily) Group 3: Risperidone Receiver (1-6 mg daily)

Main outcome variables

Delirium score based on the Intensive Care Delirium Screening Checklist

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190404043159N3**

Registration date: **2021-04-02, 1400/01/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-02, 1400/01/13**

Update count: **0**

Registration date

2021-04-02, 1400/01/13

Registrant information

Name

Mohammad Reza Sharbafchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3222 2475

Email address

sharbafchi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and Comparison of the Effect of Haloperidol, Risperidone, and Quetiapine Medications in the Treatment of Delirium in End-stage Cancer Patients

Public title

Evaluation of the Effect of Haloperidol, Risperidone, and Quetiapine in the Delirium of Cancer Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of any Type of End-stage Cancer Informed Consent of the Patient or Family More than 18 Years Old Diagnosis of Delirium Disorder According to DSM-V Criterion

Exclusion criteria:

Presence of Major Neurocognitive Disorder Contraindication for Consumption of Antipsychotic Medications

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Treatment methods are identified as A, B, and C. Individuals are divided into 3 groups by the random block method. In this way, the first 3 qualified people are selected and included in the study. These 3 people are considered as a triple block and are arranged according to the last digit of the national code. We identify all three compounds and decode them after the last prescription of the drugs for the last block.

Blinding (investigator's opinion)

Double blinded

Blinding description

One person randomizes individuals into three groups and then adjusts the daily dose of the drug until a therapeutic response is achieved. The second person, who has no information about the type of drug used, evaluates patients on a daily basis using a questionnaire and provides the results to the doctor who adjusts the dose of the drug 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

No. 18, Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-09-11, 1399/06/21

Ethics committee reference number

IR.MUI.MED.REC.1399.482

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

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

2**Description of health condition studied**

Malignancy

ICD-10 code

C80.1

ICD-10 code description

Malignant (primary) neoplasm, unspecified

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

Delirium Score in Intensive Care Delirium Screening Checklist

Timepoint

Before the intervention and daily for up to 7 days after remission

Method of measurement

Intensive Care Delirium Screening Checklist

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Abidi's haloperidol tablets (1-6 mg daily) starting with the minimum dose and increasing daily until the delirium symptoms improve or the drug dose is reached.

Category

Treatment - Drugs

2

Description

Second Intervention group: Abidi's Quetiapine tablets (25-400 mg daily) starting with the minimum dose and increasing daily until the delirium symptoms improve or the drug dose is reached.

Category

Treatment - Drugs

3

Description

Third Intervention group: Abidi's Risperidone tablets (1-6 mg daily) starting with the minimum dose and increasing daily until the delirium symptoms improve or the drug dose is reached.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Research, Educational, Therapeutic Complex

Full name of responsible person

Mohammad Reza Sharbafchi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

100

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

Mohammad Reza Sharbafchi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments