

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the impact of palliative care supportive treatment on the symptoms of cancer patients in the final stage 2022-2023

Protocol summary

Study aim

The effect of supportive palliative medicine treatment on the symptoms of terminally ill cancer patients in Imam Khomeini Hospital

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 15 patients. The randomization function of Excel software was used for randomization.

Settings and conduct

A clinical trial is conducted at Imam Khomeini Hospital, who refer to the palliative medicine clinic

Participants/Inclusion and exclusion criteria

The entry conditions of cancer patients in the final stages and the non-entry of cancer patients who receive specific treatments for the disease.

Intervention groups

The intervention in the control group is not receiving psychotherapy and in the intervention group psychotherapy.

Main outcome variables

Wasting the patient's time to fill out the questionnaire

General information

Reason for update

Due to numerous corrections in the trial registration and prolongation of approval in IRCT, the start and end date of sampling was changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058320N1**

Registration date: **2023-10-04, 1402/07/12**

Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**

Update count: **1**

Registration date

2023-10-04, 1402/07/12

Registrant information

Name

Nakisa Soleymanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 919 169 3774

Email address

mydigital.market1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-09, 1402/07/17

Expected recruitment end date

2023-11-09, 1402/08/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of palliative care supportive treatment on the symptoms of cancer patients in the final stage 2022-2023

Public title

Investigating the effect of palliative medicine on the symptoms of cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients in the final stages of cancer End-stage cancer patients referred to palliative medicine clinic of Imam Khomeini Hospital All patients in the final stages of hematological cancers All cancer patients who do not

receive special cancer treatment End-stage cancer patients referred to internal clinic of Imam Khomeini Hospital

Exclusion criteria:

Patients receiving specific cancer treatment Cancer patients who visit the surgery clinic Cancer patients receiving chemotherapy Cancer patients candidates for surgery Cancer patients candidates for radiotherapy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 15

Randomization (investigator's opinion)

Randomized

Randomization description

Questionnaires are given to people randomly with the help of a random number table in the internal clinic, and in the same way, the questionnaire is given in the palliative medicine clinic. The people of the two study groups do not know about the other group

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients who refer to the palliative medicine clinic do not know about the patients who refer to the internal clinic

Placebo

Not 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

Emam Khomeini Hospital, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-05-09, 1402/02/19

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.041

Health conditions studied

1

Description of health condition studied

End stage cancer

ICD-10 code

Z85.8

ICD-10 code description

Personal history of malignant neoplasms of other organs and systems

Primary outcomes

1

Description

Questionnaire of sleep quality, appetite and depression

Timepoint

Filling out the questionnaire at the first visit and then four weeks later.

Method of measurement

Questionnaire for the effect of supportive treatments on patients' symptoms

2

Description

appetite

Timepoint

sleep

Method of measurement

depression

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention includes psychotherapy and the patient's conversation with the doctor and creating empathy during a ten-minute session and symptomatic treatment according to the patient's complaints, including constipation or diarrhea or weakness and fatigue or feelings of hopelessness and sleep problems.

Category

Treatment - Other

2

Description

Control group: This group goes to the internal clinic due to physical problems and receives the desired treatment according to the complaint, but the psychotherapy

session and the patient's mental problems are not discussed.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeini hospital.

Full name of responsible person

Nakisa Solymanian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Foutouhi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

80

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**

Tehran University of Medical Sciences

Full name of responsible person

Nakisa Solymanian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data**Contact**

Name of organization / entity

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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