

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effectiveness of symptom control in palliative care on the quality of life of cancer patients referred by oncologists

Protocol summary

Study aim

Since one of the ways to improve the quality of life in cancer patients is to control the symptoms and complications caused by cancer, therefore, the investigation and management of these symptoms become very important. The purpose of this study is to investigate the effectiveness of controlling the symptoms of cancer patients in palliative care on their quality of life.

Design

This research constitutes a pre-post interventional clinical trial to be conducted on a cohort of 90 individuals diagnosed with one type of cancer.

Settings and conduct

This study will be conducted in Imam Khomeini Hospital in Tehran. Patients referring to the oncologist who have annoying symptoms related to cancer will be referred to a palliative medicine specialist through a letter. Then, based on the severity of the annoying symptoms and the physical needs of the person, a symptom control program, specific to each patient, in the form of drug interventions and also Counseling sessions for psychology, spirituality, nutrition, etc. will be available to patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a definite cancer diagnosis with the opinion of an oncologist Having a score of at least 4 in one of the annoying symptoms such as pain or other physical symptoms The patient in the final phase of the disease and with a survival of less than one month will be excluded from the study

Intervention groups

Symptom control includes managing annoying physical symptoms such as pain, digestive symptoms (nausea, vomiting, constipation, diarrhea, etc.), respiratory symptoms (shortness of breath, cough, etc.), neurological symptoms (delirium, headache, etc.) and other symptoms that will be performed in the outpatient clinic in the form of pharmacological and non-

pharmacological interventions.

Main outcome variables

Severity score of common symptoms in cancer patients and their quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057851N1**

Registration date: **2023-05-07, 1402/02/17**

Registration timing: **prospective**

Last update: **2023-05-07, 1402/02/17**

Update count: **0**

Registration date

2023-05-07, 1402/02/17

Registrant information

Name

Adeleh Rezagholizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2530

Email address

adelehgholizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of symptom control in palliative care on the quality of life of cancer patients referred by oncologists

Public title

Evaluation of the effectiveness of symptom control in patients with cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a definite cancer diagnosis with the opinion of an oncologist Physical and mental ability to communicate and complete questionnaires Having a score of at least 4 in one of the annoying symptoms such as pain or other physical symptoms Patient availability during the 2-week study period First referral to the palliative care service

Exclusion criteria:

The patient is in the final phase of the disease Prediction of survival of less than one month for the patient

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

مجتمع بیمارستانی امام خمینی ره- دانشگاه علوم پزشکی تهران
(کمیته اخلاق در پژوهش)

Street address

Imam Khomeini Hospital Complex, Tohid Squire,

Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.455

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

Advanced Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasm

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

The intensity score of common symptoms experienced by cancer patients in the Edmonton Symptom Assessment Scale questionnaire

Timepoint

Time intervals for evaluation at the beginning of the study (before the cancer symptom management plan), and by passing 7, and 14 days from the intervention (Follow-up)

Method of measurement

Edmonton Symptom Assessment Scale questionnaire (ESAS)

2**Description**

Quality of life in cancer patients

Timepoint

Time intervals for evaluation at the beginning of the study (before the cancer symptom management plan), and by passing 7, and 14 days from the intervention (Follow-up)

Method of measurement

The European Organization for Research and Treatment of Cancer core quality of life questionnaire (EORTC-QLQ-C30)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A personalized cancer symptom management plan, designed by a palliative medicine specialist, which includes pharmacological and non-pharmacological interventions (psychological, spiritual, nutritional counseling sessions, etc.) in the outpatient clinic.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Adeleh Rezagholizadeh Shirvan

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Tohid Squire, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Adeleh Rezagholizadeh Shirvan

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Adeleh Rezagholizadeh Shirvan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Palliative Medicine

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Person responsible for updating data

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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