Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Squre, 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-C۳۰)

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

Street address
Tohid Squre, Tehran, Iran

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adelehgholizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Adeleh Rezagholizadeh Shirvan

Street address
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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 scientific inquiries

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Full name of responsible person
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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