

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Nanocurcumin role as an adjunctive therapy on treatment response and quality of life in patients with breast and gastrointestinal cancer resistant to treatment: Randomized clinical trial

Protocol summary

Summary

Curcumin is a lipid-soluble compound extracted from the plant *Curcuma Longa* and can potentially prevent cancer development with no discernible toxicity. However, absorption, distribution, metabolism and excretory studies of curcumin in recent years focus on its low bioavailability in systemic circulation. Subsequently, many methods were tested to overcome this defect like the use of nanocurcumin. Our previous results shed new light on the potential biocompatibility, biodegradability and anticancer effects of nanocurcumin in the preclinical studies. Furthermore, our data in clinical phase I study showed that nanocurcumin can be tolerated even in high doses without any toxicity. Therefore, in the present study, we aimed nanocurcumin role as an adjunctive therapy with standard therapy on treatment response and quality of life in patients with breast and gastrointestinal cancer resistant to treatment. 40 patients were randomly selected into control and case groups; with breast cancer and colon cancer, referred to Institute cancer of Iran, from September 2014 to September 2015. The Functional Assessment of Cancer Therapy (FACT) and Questionnaire for Cancer Rehabilitation Evaluation System (CARES), and CT scan are used for estimation of quality of life and response to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091418745N2**

Registration date: **2014-10-09, 1393/07/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-09, 1393/07/17

Registrant information

Name

Ali Mohammad Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2501

Email address

aalizadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Nanocurcumin role as an adjunctive therapy on treatment response and quality of life in patients with breast and gastrointestinal cancer resistant to treatment: Randomized clinical trial

Public title

Nanocurcumin role in patients with breast and gastrointestinal cancer resistant to treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Randomize; Pathology report of invasive breast and GI carcinoma; signed informed consent; resistant to treatment; metastatic disease.
Exclusion criteria: Less than 50% heart ejection fraction; heart failure; liver failure (liver enzymes more than 5 times of upper normal limit) or creatinine more than 2 mg/dl; low albumin < 2; brain metastasis; severe diarrhea.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Bulvar, Porsina Street

City

Tehran

Postal code

134511345

Approval date

2014-02-01, 1392/11/12

Ethics committee reference number

92-01-51-21039-92287

Health conditions studied

1

Description of health condition studied

Breast and GI cancers

ICD-10 code

c50-c50 an

ICD-10 code description

Breast, unspecified; Malignant neoplasms of digestive organs

Primary outcomes

1

Description

Response to treatment

Timepoint

Before and after drug therapy, 3 months

Method of measurement

CT scan

Secondary outcomes

1

Description

The assesment of quality of life

Timepoint

Before and after of treatment, 3 months

Method of measurement

Questionnaires of FACT and CARES

Intervention groups

1

Description

12 tablet of nanocurcumin placebo per a day (3 tablet, QID) for three months except during chemotherapy

Category

Placebo

2

Description

12 tablet of nanocurcumin per a day (3 tablet, QID) for three months except during chemotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Iran

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Street address

Keshavarz Bulvar, Institut of Cancer

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Uonesian

Street address

Keshavarz Bulvar, Porsina Street.

City

Tehran

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

Yes

Title of funding source

Vice-chancellor for Research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Position

Ph.D, Assistant Professor

Other areas of specialty/work**Street address**

Keshavarz Bulvar, Cancer Institute of Iran, Cancer Research Center

City

Tehran

Postal code

13145158

Phone

+98 21 6119 2501

Fax

+98 21 6119 2501

Email

aalizadeh@razi.tums.ac.ir

Web page address

www.pccrg.org

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahdi Aghili, Dr. Ali Mohammad Alizadeh

Position

Associated professor, Assistant professor

Other areas of specialty/work**Street address**

Keshavarz Bulvar, Cancer Institute of Iran

City

Tehran

Postal code

13145158

Phone

+98 21 6694 8672

Fax

+98 21 6119 2501

Email

aghili@tums.ac.ir

Web page address

www.pccrg.org

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical of Sciences

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Position

Ph.D, Assistant Professor

Other areas of specialty/work**Street address**

Keshavarz Bulvar, Institut of Cancer, Cancer Research Center

City

Tehran

Postal code

13145158

Phone

+98 21 6119 2501

Fax

+98 21 6119 2501

Email

aalizadeh@razi.tums.ac.ir

Web page address

www.pccrg.org

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty