

# 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**

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## Person responsible for scientific inquiries

### Contact

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Dr. Mahdi Aghili, Dr. Ali Mohammad Alizadeh

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Associated professor, Assistant professor

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## Person responsible for updating data

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Tehran University of Medical of Sciences

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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*