

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Evaluation of curcumin effect on prevention of hepatotoxicity induced by chemotherapeutic drugs in patients under outpatient cancer treatment

Protocol summary

Study aim

determining the preventive effect of curcumin on chemotherapy induced hepatotoxicity in patient with cancer

Design

double blinded randomized control clinical trial with parallel group design of 120 patients. we used random allocation software for randomization.

Settings and conduct

the study will be performed in Milad Hospital of Isfahan on cancer patients receiving taxanes, by dividing the subjects into control group and intervention, by randomization and researcher blinding methods.

Participants/Inclusion and exclusion criteria

including criteria 1-age between 30 and 60 2-definite diagnosis of cancer with chemotherapy indication 3-chemotherapy with paclitaxel and docetaxel excluding criteria 1- taking Heparin, aspirin, clopidogrel, dipyridamol, warfarin, ticlopidine 2- pregnancy and lactation 3- past history of liver disease 4- peptic ulcer 5- gastrointestinal bleeding

Intervention groups

This study is a double-blind randomized controlled clinical trial of parallel groups to evaluate the prophylactic effect of Curcumin on cancer-induced hepatotoxicity. In this study, 60 cancer patients treated with DOCATAXLE or PICATAXLE met the inclusion criteria. They are randomly divided into 4 groups of control and treatment with 30 patients in each group. The treatment group receives one 450 mg Curcumin tablet per day, while the control group receives one tablet per day. Placebo receives. In both groups, at intervals before the intervention, 3 and 6 weeks after the intervention, ALT, AST, BILIRUBIN, ALP tests are performed by a laboratory that does not know the groups. Hepatotoxicity is determined by increasing each of these enzymes from the normal range. , Will be registered.

Main outcome variables

liver enzyme

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190918044815N1**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **retrospective**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name

Danial Abasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3625 8246

Email address

sohrab137347@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

2020-02-20, 1398/12/01

Actual recruitment end date

2020-07-22, 1399/05/01

Trial completion date

Scientific title

Evaluation of curcumin effect on prevention of hepatotoxicity induced by chemotherapeutic drugs in patients under outpatient canecr treatment

Public title

Evaluation of curcumin effect on prevention of hepatotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 30 to 60 years Definitive diagnosis of cancer that chemotherapy treatment is indicated . Treated with a regimen containing paclitaxel and docetaxel Ability to take oral medication

Exclusion criteria:

Gastrointestinal bleeding pregnancy and Breastfeeding using heparin, aspirin, Clopidogrel, dipiridamol ,warfarin and ticlopidine Past medical history of hepatic disease Past medical history of peptic ulcer

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization was performed using random allocation software. The randomization method was of permutation block type with blocks of volume 4. For each person who entered the study, a code was obtained from the software and it was determined which group it belongs to (intervention or control).

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blinded study.in this study patients,outcome evaluator and statistical analyzer are blind.each patient is belong to group A or B and only the researcher knows which group is intervention group and which is control group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan university of medical sciences

Street address

Hezarjarib Ave

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Postal code

81746-73461

Approval date

2020-02-14, 1398/11/25

Ethics committee reference number

IR.MUI.MED.REC.1398.579

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

cancer

ICD-10 code

C50.1

ICD-10 code description

Malignant neoplasm of central portion of breast

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

Aspartate Aminotransferase

Timepoint

before intervention and 3 and 6 weeks after intervention

Method of measurement

laboratory

2**Description**

alanine transaminase

Timepoint

before intervention and 3 and 6 weeks after intervention

Method of measurement

laboratory

3**Description**

Alkaline phosphatase

Timepoint

before intervention and 3 and 6 weeks after intervention

Method of measurement

laboratory

4**Description**

bilirubin

Timepoint

before intervention and 3 and 6 weeks after intervention

Method of measurement

laboratory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: At first, 30 people were randomly selected from permutation block and received a 450 mg curcumin tablet daily and at intervals before the intervention, 3 and 6 weeks after the intervention, ALT, AST, BILIRUBIN, ALP tests by A laboratory that does not know the groups will be checked and the hepatotoxicity determined by the increase of each of these enzymes from the normal range will be recorded.

Category

Treatment - Drugs

2**Description**

Control group: First, 30 people are randomly selected from the permutation block type and receive one placebo pill daily. At intervals before the intervention, 3 and 6 weeks after the intervention, ALT, AST, BILIRUBIN, ALP tests are checked by a laboratory that does not know the groups, and the hepatotoxicity is determined by increasing each of these enzymes from the normal range. Will be registered.

Category

Placebo

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

Milad hospital

Full name of responsible person

Dr Ali Hajigholami

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

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Ali Hajgholami

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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