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 canecr treatment

Protocol summary

Study aim
determining the preventive effect of corcomin 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, dipiridamol, 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 diet 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)

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+98 31 3625 8246

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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

2020-07-22, 1399/05/01

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 chemotherapyeutic 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

City
Isfahan

Province
Isfehan

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
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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
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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