

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy and safety of Detoxil (a herbal medicine) in improving liver function in liver injury

Protocol summary

Study aim

Evaluation of the efficacy and safety of Detoxil (a herbal medicine) in improving liver function in liver injury

Design

A randomized, placebo-controlled, double-blinded, parallel phase 3 clinical trial

Settings and conduct

In this study, 100 eligible patients admitted to Baqiyatallah Hospital who have obtained their informed and informed consent will participate the study. Patients are randomly divided into two groups intervention and control with an equal sample size (50:50). Each patient will be in the study for 5 days. Before and after the intervention, the patient will be evaluated and the results will be recorded in the form and at the end will be analyzed through SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient must be over 18 years old; The patient's Child-Pugh score is category B and C; The patient or his / her companion has informed and free written consent to participate in the study. Exclusion criteria: Pregnancy; Breastfeeding; History of previous allergies to any of the active ingredients of the drug; Concomitant presence in another clinical study;

Intervention groups

Intervention group: oral Detoxil capsule 400mg, 1 capsule every 12 hours, for 5 days. Placebo group: oral Placebo capsule 400mg, 1 capsule every 12 hours, for 5 days.

Main outcome variables

Changes in serum level of ALT enzyme; Changes in serum level of AST enzyme;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N68**

Registration date: **2022-09-14, 1401/06/23**

Registration timing: **prospective**

Last update: **2022-09-14, 1401/06/23**

Update count: **0**

Registration date

2022-09-14, 1401/06/23

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of Detoxil (a herbal medicine) in improving liver function in liver injury

Public title

Evaluation of efficacy and safety of Detoxil capsules in

patients with liver injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient has informed and free written consent to participate in the study; Age between 18-80; The patient's Child-Pugh score is category B or C;
Exclusion criteria:
Pregnancy; Breastfeeding; Participate in another clinical trial at the same time; History of previous allergies to any of the components of the drug;

Age
From **25 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization method is used to randomized the patients. In this method, the number of people assigned to each group is usually almost equal. Blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as witnesses. The main goal in this method is to balance the number of participants in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The placebo looks the same as the original drug, provided by the drug company. In this study, the prescribing physician, patient, therapeutic team, data collector, and statistical analyzer are unaware about type of intervention (intervention / placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Baqiyatallah Hospital
Street address

Baqiyatallah Hospital, Mollasadra Ave., Vanak
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2022-04-12, 1401/01/23
Ethics committee reference number
IR.BMSU.BAQ.REC.1401.002

Health conditions studied

1

Description of health condition studied
Diseases of liver
ICD-10 code
K76.9
ICD-10 code description
Liver disease, unspecified

Primary outcomes

1

Description
AST serum level
Timepoint
Before and after intervention
Method of measurement
Blood sample

2

Description
ALT serum level
Timepoint
Before and after intervention
Method of measurement
Blood sample

Secondary outcomes

1

Description
Bilirubin serum level
Timepoint
Before and after the intervention
Method of measurement
Blood sample

2

Description
Child-Pugh score
Timepoint
Before and after the intervention
Method of measurement
Child-Pugh score classification

Intervention groups

1

Description

Intervention group: oral Detoxil capsules 400mg, 1 capsule, every 12 hours for 5 days. Detoxil capsules are prepared by Tabib-Daru Pharmaceutical Company (located at Kashan) and contain hydroalcoholic extracts of sage, artichoke, dandelion and poppy extract with the 1:1 ratio.

Category

Treatment - Drugs

2

Description

Control group: oral placebo capsule 400mg, 1 capsule every 12 hours for 5 days. The placebo capsule with a appearance completely similar to the main drug has been prepared by Tabib-Daru Pharmaceutical Company (located at Kashan).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Yunes Panahi

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Mollasadra Street, Vanak Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyed Mohammad Zarei Abarghouee

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tabib daru pharmaceutical company

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parisa Kianpour

Position

Fellowship in Critical care Pharmacotherapy

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Position
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Latest degree
Specialist
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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