Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of effectiveness and safety of Detoxil capsules in controlling metabolic syndrome: A phase 3, randomized, placebo-controlled, double blind study

Protocol summary

Study aim

Evaluation of effectiveness and safety of Detoxil capsules in controlling metabolic syndrome

Design

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

Settings and conduct

In this study, a total of 100 patients will participate who meet the inclusion criteria and who have given conscious and free consent for participation. The patients will be randomly divided into control and intervention groups in Baqiyatallah clinic. The duration of the study will be 12 weeks. Blood sampling, liver ultrasonography and anthropometric evaluation will be performed before and after intervention and the results will be analyzed with the help of SPSS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: between 25 and 75 years; The patient have written consciously and freely consent to participate in the study; Patient should fulfill the criteria of NCEP ATP III for metabolic syndrome by having at least three items out of the following: 1- Fasting blood glucose higher than 100 mg/dL; 2- triglyceride level higher that 150 mg/dL; 3- HDL level lower than 40 mg/dL for men and 50 mg/dL for women; 4- systolic blood pressure higher than 130 mmHg or diastolic blood pressure higher than 85 mmHg; 5- waist circumference bigger than 102 cm for men and 94 cm for women. Exclusion criteria: History of allergy to this drug ingredients; The patient is in another clinical trial at the same time; active malignancies; severe hepatic or renal disease; Pregnancy; Lactation.

Intervention groups

Control group: placebo drug, 1 capsule three times daily for 12 weeks Intervention group: Detoxil drug, 1 capsule three times daily for 12 weeks

Main outcome variables

Biomarker levels in blood (LDL,HDL,TG, Total Cholesterol, FBS, A1C, ALT, AST, Bilirubin total & direct, ALK, CRP, TNF-α, IL-6, IL-8, leptin, adiponectin, SOD, MDA); liver fatty disease stage; weight; waist circumferenc; BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N65**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

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

2021-08-06, 1400/05/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of effectiveness and safety of Detoxil capsules in controlling metabolic syndrome: A phase 3, randomized, placebo-controlled, double blind study

Public title
Effectiveness of Detoxil capsules in metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient should have read and signed the informed consent form Patient should fulfill the criteria of NCEP ATP III for metabolic syndrome by having at least three items out of the following: 1- Fasting blood glucose higher than 100 mg/dL; 2- triglyceride level higher that 150 mg/dL; 3- HDL level lower than 40 mg/dL for men and 50 mg/dL for women; 4- systolic blood pressure higher than 130 mmHg or diastolic blood pressure higher than 85 mmHg; 5- waist circumference bigger than 102 cm for men and 94 cm for women
Exclusion criteria:
Pregnancy Lactation Participation at a concurrent clinical trial History of allergic reaction to any of the ingredients of drug Active malignancy Severe hepatic or renal disease
Age
From **25 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method is used to randomized the patients. For randomization, we visited the www.sealedenvelope.com, then randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (which was selected due to the small sample size, 4)were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
The appearance of drug and placebo capsules will be identical in the study. Only the DSMB and data statistician will be aware of the contents of the capsules. Therefore, other involved people including the researcher, clinical assessor and the participants are not informed of the type of intervention.
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, Sheykh-e-Baha'ee, Sare Mollasadra
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2021-06-26, 1400/04/05
Ethics committee reference number
IR.BMSU.BAQ.REC.1400.014

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Blood pressure
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mmHg

2

Description

Triglyceride
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/dL

3

Description
LDL
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/dL

4

Description
HDL
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/dL

5

Description
Total cholestrol
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/dL

6

Description
FBS
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/dL

7

Description
HbA1c
Timepoint
Before and after intervention (12 weeks)
Method of measurement
serum levels

8

Description
Weight
Timepoint
Before and after intervention (12 weeks)
Method of measurement
kg

9

Description
Waist circumference
Timepoint
Before and after intervention (12 weeks)
Method of measurement
cm

10

Description
Fatty liver disease stage
Timepoint
Before and after intervention (12 weeks)
Method of measurement
Ultrasonography

Secondary outcomes

1

Description
BMI
Timepoint
Before and after intervention (12 weeks)
Method of measurement
kg/m2

2

Description
ALT
Timepoint
Before and after intervention (12 weeks)
Method of measurement
U/L

3

Description
AST
Timepoint
Before and after intervention (12 weeks)
Method of measurement
U/L

4

Description
ALP
Timepoint
Before and after intervention (12 weeks)
Method of measurement
U/L

5

Description
total bilirubin
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/dL

6

Description
Direct bilirubin
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/dL

7

Description
MDA
Timepoint
Before and after intervention (12 weeks)
Method of measurement
nmole/mL

8

Description
SOD
Timepoint
Before and after intervention (12 weeks)
Method of measurement
IU/mL

9

Description
Leptin
Timepoint
Before and after intervention (12 weeks)
Method of measurement
ng/mL

10

Description
Adiponectin
Timepoint
Before and after intervention (12 weeks)
Method of measurement
µg/mL

11

Description
IL-6
Timepoint
Before and after intervention (12 weeks)
Method of measurement
serum levels

12

Description
IL-8
Timepoint
Before and after intervention (12 weeks)
Method of measurement
serum levels

13

Description
CRP
Timepoint
Before and after intervention (12 weeks)
Method of measurement
mg/L

14

Description
TNF-α
Timepoint
Before and after intervention (12 weeks)
Method of measurement
serum levels

Intervention groups

1

Description
Intervention group: Detoxil capsule three times daily for 12 weeks. Detoxil capsules were manufactured in Tabib Darou company and contain the hydroalcoholic extracts of milk thistle, artichoke, dandelion and burdock. 60% of the capsule is comprised of artichoke extract and the rest is divided between other three extracts equivalently.
Category
Treatment - Drugs

2

Description
Control group: placebo capsules three times daily for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Baqiyatallah Hospital
Full name of responsible person
Dr. Yunes Panahi
Street address
Mollasadra Street, Vanak Square
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabib daru pharmaceutical company
Full name of responsible person
Mahboube Mahoubi
Street address
Homa Building, Unit 3, Shahid Motahhari Boulevard, Kashan, Alley
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Isfehan
Postal code
1435915371
Phone
+98 31 5557 1000
Email
Mahboubi1357@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabib daru pharmaceutical company
Proportion provided by this source
100
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ali Ahmadi
Position
Pharmacist
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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