Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

The effect of treatment of non-alcoholic fatty liver with zucchini in pregnant women on the gestational diabetes

Protocol summary

Study aim
The effect of treatment of non-alcoholic fatty liver with zucchini in pregnant women on the gestational diabetes

Design
In this randomized clinical trial, 60 consecutive pregnant women with non-alcoholic fatty liver, were randomly divided into 2 groups of intervention and control

Settings and conduct
In this randomized clinical trial , 60 consecutive pregnant women with non-alcoholic fatty liverattending to Kosar Obstetrics Clinic in Arak were enrolled. They were randomly divided into 2 groups of intervention and control. The first group received zucchini 100 gr daily plus dietary regimen for 6 weeks and the control group received just dietary regimen

Participants/Inclusion and exclusion criteria
Inclusion criteria: Known cases of non-alcoholic fatty liverwomen with age between 20-35 years. Exclusion: Alcohol users, other chronic hepatic diseases, known cases of Diabetes mellitus under medical treatment

Intervention groups
In Intervention group they used zucchini 100 gram daily plus dietary regimen for 6 weeks and in control group they were just under dietary regimen

Main outcome variables
Pregnancy Diabetes, Liver Enzyme Level, Lipid Profile Level, Fasting Blood Sugar Level, TNFα Level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200419047137N1**
Registration date: **2020-05-05, 1399/02/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-05, 1399/02/16**
Update count: **0**

Registration date
2020-05-05, 1399/02/16

Registrant information
Name
Anahita Haghjoo jahromi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-12-22, 1398/10/01
Expected recruitment end date
2020-12-21, 1399/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of treatment of non-alcoholic fatty liver with zucchini in pregnant women on the gestational diabetes

Public title
The effect of treatment of non-alcoholic fatty liver with zucchini in pregnant women on the gestational Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-35 years old Known case of non-

alcoholic fatty liver

Exclusion criteria:

Alcohol user Known cases of autoimmune hepatitis, Hepatitis B, Hepatitis C, or other chronic hepatic diseases Known cases of Diabetic Mellitus under treatment Patients who use Vitamin C, Zinc, Mn or the other antioxidants Patients who use Fibrate, Statins, NSAIDs, Amiodarone or Tamoxifen

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization; randomization with envelopes and allocating into two groups A and B. In this method, we select a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards are mixed. One card is taken out and its allocation is registered and the card is returned to the box near other cards. Then the cards are mixed again and we take out another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Arak University of Medical Sciences

Street address

Imam-Khomeini Boulevard, Taleghani Hospital

City

Arak

Province

Markazi

Postal code

3814156634

Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.ARAKMU.REC.1398.269

Health conditions studied

1

Description of health condition studied

Non-alcoholic Fatty Liver , Gestational Diabetes Mellitus

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Incidence of gestational diabetes

Timepoint

6 weeks

Method of measurement

Glucose Tolerance Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant women with non-alcoholic fatty liver who are on a diet of 100 grams of zucchini daily for 6 weeks.

Category

Treatment - Other

2

Description

Control group: The control group is on a regular diet alone.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Anahita Haghjoo Jahromi

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Sponsors / Funding sources

1

Sponsor
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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
Arak 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
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Position
Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When the article is published, the Excel data file will be available.

When the data will become available and for how long

6 months after publishment of article

To whom data/document is available

Public Use

Under which criteria data/document could be used

Academic researchers can request unrecognizable data after the article is published.

From where data/document is obtainable

Dr Nazila Najdi Faculty of Arak University of Medical Sciences Email: n.najdi@arakmu.ac.ir

What processes are involved for a request to access data/document

They have to write email to the professors corresponding. Email:n.najdi@arakmu.ac.ir Estimated time to respond:1 months

Comments