

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of banana and date consumption by pregnant mother on the reactivity of non-reactive fetus NST test

Protocol summary

Study aim

The effect of banana and date consumption by pregnant mother on non-reactive fetal heart rate reactivity

Design

In this phase 3 clinical trial, with a control group, by using random number table 160 participants in this study into 4 groups including: group A (consumption of one banana and 500 cc of water), group B (consumption of 7 dates and 500 cc of water), group C (consumption of 500 cc of water and 25 grams of glucose) and the control group(D)(consumption of 500 cc of water) were divided. This study is not blinded.

Settings and conduct

In this clinical trial without blinding, 160 pregnant women with 37 weeks of pregnancy and more referring to the midwifery clinic of Hajar Hospital to perform fetal heart rate reactivity are randomly assigned to four groups. In order to evaluate the effect of dates, bananas, glucose are studied

Participants/Inclusion and exclusion criteria

Inclusion criteria: • singleton pregnancy. • Pregnancy age 36-40 weeks. • Non-reactive test without stress. • The normality of the basic heart rate of the fetus (110-160) Exclusion criteria: • Multiple pregnancy • Mother's history or suffering from diseases such as diabetes, blood pressure, heart, kidney and thyroid diseases • Fetus with intrauterine growth restriction • Rupture of water sac or reduction of amniotic fluid

Intervention groups

The intervention groups include: group A (consumption of one banana and 500 cc of water), group B (consumption of 7 dates and 500 cc of water), group C (consumption of 500 cc of water and 25 grams of glucose) and control group(D) (consumption of 500 cc of water) Water)

Main outcome variables

Non-Reactive Fetal heart rate reactivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160709028844N3**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **retrospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Sheida Shabanian

Name of organization / entity

Shaharekord University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 38 3228 4014

Email address

shabanian@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-22, 1397/05/31

Expected recruitment end date

2019-01-19, 1397/10/29

Actual recruitment start date

2018-10-22, 1397/07/30

Actual recruitment end date

2019-03-19, 1397/12/28

Trial completion date

2019-04-29, 1398/02/09

Scientific title

Comparison of the effect of banana and date consumption by pregnant mother on the reactivity of non-reactive fetus NST test

Public title

The effect of banana and date consumption on the reactivity of non-reactive fetus NST test

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Single pregnancy Pregnancy age 36-40 weeks Non-reactive test without stress The normality of the basic heart rate of the fetus (110-160) Fetal health according to ultrasound evidence Mother fasting (three hours before the test) Normal body mass index

Exclusion criteria:

Multiple pregnancy Mother's history or suffering from diseases such as diabetes, blood pressure, heart, kidney and thyroid diseases The use of painkillers, narcotics and sedatives and drugs affecting uterine contractions by the mother Fetus with intrauterine growth restriction Vaginal bleeding Rupture of water sac or reduction of amniotic fluid Beginning of uterine contractions Allergy to bananas or dates Unwillingness to cooperate

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the simple randomization method, the participants are assigned to 4 groups. For this purpose, 160 identical cards, on which 40 letters A, 40 letters B, 40 letters C, and 40 letters D are inserted, are mixed in an envelope and one card is randomly drawn for each participant. The letter inserted on the card will show the treatment group of the patient.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Kashani street

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

IR.SKUMS.REC.1397.302

Health conditions studied

1

Description of health condition studied

Non-reactive fetal heart rate

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Non-Reactive Fetal heart rate

Timepoint

Before and after the intervention, the fetal heart rate test will be recorded. If there are 2 times of increasing the heart rate of the fetus by the number of 15 from the base line for 15 seconds, the result is Reactive

Method of measurement

before and after the intervention, the fetal heart rate test will be recorded and studied. The fetal heart rate test is recorded on both occasions by a computerized device, and if there are 2 times of increasing the heart rate of the fetus by the number of 15 from the base line for 15 seconds, the result is Reactive.

2

Description

Before and one hour after the intervention, the blood sugar of the participants will be measured and recorded.

Timepoint

Before and one hour after the intervention, the blood sugar of the participants will be measured and recorded with a glucometer.

Method of measurement

Glucometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: consumption of one banana and 500 cc of water

Category

Treatment - Other

2

Description

Intervention group B: Consumption of 7 dates and 500 cc of water

Category

Treatment - Other

3

Description

Intervention group C: Consumption of 500 cc of water and 25 grams of glucose

Category

Treatment - Other

4

Description

Control group(D): Consumption of 500 cc of water

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Midwifery Clinic of Hajar Hospital

Full name of responsible person

Sheida Shabanian

Street address

Parastar street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Phone

+98 38 3228 4014

Email

sheidashabanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Reisi

Street address

Shahrekord, Kashani Blvd, University Headquarters

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3333 0061

Email

info@skums.ac.ir

Grant name

Research credits of Shahrekord University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Sheida Shabanian

Position

Assistant Professor of Shahrekord University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 4, Yaser St. 36

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815754673

Phone

+98 38 3228 4014

Email

sheidashabanian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Sheida Shabanian

Position

Assistant Professor of Shahrekord University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 4, Yaser St. 36

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815754673

Phone

+98 38 3228 4014

Email

sheidashabanian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Sheida shabanian

Position

Assistant Professor of Shahrekord University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 4, Yaser St. 36

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815754673

Phone

+98 38 3228 4014

Email

sheidashabanian@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address sheidashabanian@yahoo.com or the contact number 009891103122195.

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments