Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A Randomized Controlled Trial to Compare the Effect of Oral Carbohydrate Intake or Fasting in Low-risk Women during Labor Progress

Protocol summary

Summary

Background and Objectives: Lack of information regarding biochemical changes in women during labor and it's outcomes on maternal and neonatal health was the main reason for conducting the trial. Our objectives were to determine the effect of oral carbohydrate intake during labor on the duration of the active phase and other maternal and neonatal outcomes. Design: A parallel prospective randomized controlled trial. Setting, and Conducts: The study conducted between September 2008 and April 2009, at the University Affiliated Teaching Hospital in Gonabad. Participants: 177 women were randomly assigned to an intervention group (N=97) or control group (N=90). Inclusion and Exclusion Criteria: Inclusion criteria were low-risk women with singleton cephalic presentation; and cervical dilatation 3-4 cm. Exclusion criteria were cesarean section; fast labor; and fetal compromise. Interventions: Women generally were unaware of group allocation. Women in the carbohydrate group have been advised to consume based on their own preferences, three medium dates with 110 ml water; or three dates with 110 ml light tea without sugar; or 110 ml industrial orange juice. The protocol is only run once but women ate and drank gradually before second stage of labor. Women assigned to the control group were asked to consume just water as routine practice. Results: Differences between duration of the active phase of labor was assessed as primary outcome measure. Other maternal and neonatal outcomes were the frequency of vomiting, type of delivery, need for augmentation of labor, analgesia, and neonatal outcomes that were considered as secondary outcome measures

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105155805N2**

Registration date: **2011-05-31, 1390/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-31, 1390/03/10

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Faculty of Nursing & Midwifery, Tehran University of Medical sciences. Dates: 05/01/2008-14/69/250/ص

Expected recruitment start date

2008-03-04, 1386/12/14

Expected recruitment end date

2008-06-14, 1387/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Controlled Trial to Compare the Effect of Oral Carbohydrate Intake or Fasting in Low-risk Women

during Labor Progress

Public title
Oral carbohydrate intake on labor progress
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion and Exclusion Criteria: Inclusion criteria were low-risk women; singleton cephalic presentation; and cervical dilatation 3-4 cm. Exclusion criteria were cesarean section; fast labor; and fetal compromise
Age
From **19 years** old to **33 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **187**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No.106, 6th Floor, Central Bldg. for TUMS , Ghods St.,Keshavarz Blvd.
City
Tehran
Postal code
1417653761
Approval date
2008-01-05, 1386/10/15
Ethics committee reference number
14/69/250/ص

Health conditions studied

1

Description of health condition studied
Delivery
ICD-10 code
080
ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Duration of active phase of labor
Timepoint
From dilatation 3-4 Cm to the complete dilatation
Method of measurement
Every 5 minutes

Secondary outcomes

1

Description
Frequency and volume of vomiting
Timepoint
Every 5 minutes
Method of measurement
By mesaurment glass based on miiliter and recheck with syringe 10 ml

2

Description
Neonate heart rates
Timepoint
First and second stage of labor
Method of measurement
By External electronic fetal heart monitoring

3

Description
Apgar scores
Timepoint
One minute and five minutes after birth
Method of measurement
Standard method based on minute

4

Description
Birth weight
Timepoint
After Birth
Method of measurement
The Neonate Scale was tested for accuracy with 100 gram weight

Intervention groups

1

Description

The women were randomly assigned to two groups. Women generally were unaware of each other groups. Women in the carbohydrate group were advised to consume three medium dates with 110 ml water; or three dates with 110 ml light tea without sugar; or 110 ml orange juice drink based on their preferences. The protocol is only run once but women ate and drank gradually before second stage of labor.

Category

Treatment - Drugs

2

Description

Women assigned to the control group were asked to consume just water as routine practice..

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Roghayeh Rahmani, roghaiehrahmany@yahoo.com

Street address

Gonabad University of Medical Sciences

City

Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Sciences Vice Chancellor for Reasearch, Tehran University of Medical Sciences (TUMS)

Full name of responsible person

Dr. Akbar Fotohi

Street address

No.106, 6th Floor, Central Bldg. for TUMS , Ghods St.,Keshavarz Blvd.

City

Tehran

Grant name

بودجه معمول جهت تحصیلات تکمیلی

Grant code / Reference number

Dates: 05/01/2008-14/69/250/ص

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

Yes

Title of funding source

Medical Sciences Vice Chancellor for Reasearch, Tehran University of Medical Sciences (TUMS)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery,Tehran University of Medical Sciences

Full name of responsible person

Parvaneh Yavari

Position

Assisstant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty