

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Clinical trial of comparison of vitamin C and E supplements effect on total antioxidant capacity of healthy women's breast milk in experimental and control groups

Protocol summary

Summary

In this study, 60 healthy women aged from 20 to 50, along with their 1 to 6-month infants were selected from a Health Center in Birjand. The aim of this study was evaluating the effect of vitamin C and E supplements on the total antioxidant capacity of human's milk. Exclusion criteria included the formula-feed for the infants and major illnesses (diabetes, infectious diseases, and genetic diseases) of both mothers and infants. Mothers and their infants were divided randomly and alternately into an experimental group and a control group. The mothers in the experimental and control groups were on free diet. Mothers in the experimental group were given 30 effervescent tablets of vitamin C (500 mg) and 30 chewable tablets of vitamin E (100 IU is equal to 100 mg). They should take one tablet from each two kinds of supplements on a daily basis. The control group did not receive this intervention. At the first step, before the intervention, milk samples of right breast of all the mothers in the two groups were taken manually from 9.00 to 11.00 a.m. when the infants were not breast-fed for at least one hour. Urine samples of the infants were collected by standard urine bags. The samples were taken 30 days later again. Total antioxidant capacity of milk and infants' urine were measured by the FRAP method, and Free radical scavenging activity of the infants' urine was measured by the DPPH method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072410379N1**
Registration date: **2013-08-21, 1392/05/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-21, 1392/05/30

Registrant information

Name

Asghar Zarban

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 0388

Email address

azarban@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of vitamin C and E supplements effect on total antioxidant capacity of healthy women's breast milk in experimental and control groups

Public title

Effect of vitamin C and E supplements on mother's milk

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having 1 to 6 months of age infants who were exclusively breast-fed since birth Exclusion criteria: formula-feed for the infants, and/or major illnesses (diabetes, infectious diseases, and genetic diseases) of mothers or the infants

Age

From **20 years** old to **50 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**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, mothers were the criterion for randomization, and infants were placed in the similar group of their mothers after randomizing the mothers. The first mother and her infant were randomly placed in one of the two groups, either the experimental group or the control group, by selecting a card from two cards on which were written the terms "control" and "experimental". The other mothers together with their infants were assigned to the two groups alternately. Mothers in the experimental group were given 30 effervescent tablets of vitamin C and 30 chewable tablets of vitamin E. They should take one tablet from each two kinds of supplements on a daily basis. The control group did not receive any intervention. It is noteworthy that the mothers in the experimental and control groups were on free diet. The measurement of the antioxidant indices in infants' urine was only done with the aim of a better evaluation of the intervention effect on the antioxidant capacity of mothers' milk.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Shahid Ghaffari St., Birjand, Southern Khorasan

City

Birjand

Postal code**Approval date**

2009-02-11, 1387/11/23

Ethics committee reference number

12/73150

Health conditions studied**1****Description of health condition studied**

Effect of supplements on total antioxidant capacity of human breast milk

ICD-10 code

Z39.1

ICD-10 code description

Care and examination of lactating mother

Primary outcomes**1****Description**

Total antioxidant capacity of human breast milk

Timepoint

Before the intervention and 30 days after the intervention

Method of measurement

FRAP method

Secondary outcomes**1****Description**

Urine antioxidant capacity of the infants and free radical scavenging activity of the infants' urine

Timepoint

Before the intervention and 30 days after the intervention

Method of measurement

FRAP, DPPH methods

Intervention groups**1****Description**

Mothers in the experimental group: 30 effervescent tablets of vitamin C (500 mg) and 30 chewable tablets of vitamin E (100 IU is equal to 100 mg) were given to them, and they should take one tablet from each two kinds of supplements on a daily basis. Mothers in the control group: They received no intervention and were on free diet.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand Health Center (Number 3)

Full name of responsible person

Khalil Balali Mood

Street address

Birjand Health Center (Number 3), 5th Alley, Shahid Bargi St., Azadi Square, Birjand, Southern Khorasan

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Birjand University of Medical Sciences

Full name of responsible person

Asghar Zarban

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Birjand University of Medical Sciences, Shahid Ghaffari St., Birjand, Southern Khorasan

City

Birjand

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Birjand University of Medical Sciences

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**

Birjand University of Medical Sciences

Full name of responsible person

Asghar Zarban

Position

PhD biochemistry/ Associate professor

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Biochemistry PhD

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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