

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effect of Honey on Diarrhea and Intestinal Microflora in ICU Patients with Enteral Nutrition

Protocol summary

Summary

The purpose of this study was to evaluate the effects of an enteral diet with honey on occurrence of diarrhea, fecal microbiota and outcome of critically ill patients. In this single center, randomized, controlled double blind study, 32 patients were randomized to receive a high protein kitchen enteral diet which in study group (16 patients) has honey as 5% of its carbohydrate content. Quantitative analyses of bifidobacterium and lactobacillus species of fecal samples were assessed by Real-Time PCR on days 0 and 7. Length of stay in ICU and development of organ failure were also compared in both groups.

General information

Acronym

Honey and Enteral Nutrition

IRCT registration information

IRCT registration number: **IRCT2014010514901N3**

Registration date: **2014-01-22, 1392/11/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-22, 1392/11/02

Registrant information

Name

Zahra Vahdat Shariatpanahi

Name of organization / entity

Faculty of Nutrition and Food Sciences, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute

Expected recruitment start date

2012-09-01, 1391/06/11

Expected recruitment end date

2013-08-01, 1392/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Honey on Diarrhea and Intestinal Microflora in ICU Patients with Enteral Nutrition

Public title

Enteral Nutrition and Honey

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Age older than 18 years; No history of gastrointestinal disease; No history of Digestive tract surgery; No history of Diabetes; Without Hyperthyroidism
Exclusion criteria: Discharge before 7 days

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Faculty of Nutrition and Food Sciences, Shahid
Beheshti University of Medical Sciences

Street address

3, Baran, West Arghavan, Farahzadi Blvd., Shahrak
Qods

City

Tehran

Postal code**Approval date**

2012-09-22, 1391/07/01

Ethics committee reference number

047478

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

Diarrhea

ICD-10 code

K90.8

ICD-10 code description

Other intestinal malabsorption

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

Diarrhea

Timepoint

Daily

Method of measurement

Observation

2**Description**

fecal microbiota

Timepoint

On days 0 and 7

Method of measurement

Real-time PCR

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

Organ failure

Timepoint

Daily

Method of measurement

Clinical and Paraclinical

2**Description**

Duration of hospitalization

Timepoint

Daily

Method of measurement

Observation

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

Study: honey 5% of total calorie

Category

Treatment - Other

2**Description**

Control: None

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tajrish Shohadaa Hospital

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

National Nutrition and Food Technology Research

Institute
Full name of responsible person
 Dr Majid Hajifaraji
Street address
 3, Baran, West Arghavan, Farahzadi Blvd., Shahrak
 Qods.
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 National Nutrition and Food Technology Research
 Institute
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 Nutrition and Food Sciences, Shahid
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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