Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Sciencees, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7484

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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 Sciencees, 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 Beheshti University of Medical Sciences
Full name of responsible person
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Position
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Person responsible for updating data

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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