Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation the effect of enteral Royal jelly supplementation compared to standard enteral nutrition on gut microbiota pattern and septic complication in critically ill patients

Protocol summary

Summary

This study is designed to evaluate the effect of enteral administration Royal jelly (RJ) on gastrointestinal tract (GUT) microbiota pattern compared to nutrient currently use in diet for critically ill patients. RJ has been used as a food or dietary supplement, it is suggested that RJ may alter gut barrier function and thus reduce septic complication. This trial was approved by the Ethics Committee of Tehran University of Medical Sciences (No. IR.TUMS.REC.1395.2643), written informed consent is obtained from all participants. Subjects are recruited in Sina hospital, Tehran University of Medical Sciences, Tehran, Iran; critically ill patients aged 18-65 years with normal or near to normal GI function and at least two signs of systemic inflammatory response syndrome are included and the patients with liver failure, renal failure and immunocompromised patients are excluded. Thirty patients who is admitted to an intensive care unit (ICU) are randomized by random numbers and divided into an intervention RJ supplementation group to receive 5000 mg of RJ preparation with standard enteral nutrition 500 kcal per day (n = 15) and a control group to receive only enteral nutrition 500 kcal per day (n = 15) for one week; sample processing and serial outcome measure are performed prior to the start of the experiment and on the period of study. Gastric aspiration and fecal samples are collected and used 16S rRNA gene sequencing for profiling of the microbiota of each subject of two groups. Blood samples are collected and analyzed to determine serum Endocan levels as biomarker of endothelial dysfunction and routine biochemistry parameters. Acute Physiologic Assessment and Chronic Health Evaluation (APACHE) II scores are obtained by questionnaire. Differences between the two groups in terms of the gut microbiota based upon changes are observed in gut microbial pattern; serum levels of Endocan, APACHE II scores and septic complications or mortality are recorded and compared. Data analysis is done according to attempt to investigate effectiveness of enteral RJ supplementation and its association with microbial diversity and the metabolic functions of gut flora. Finding of the present study can be used to guiding future strategies for screening and treatment critically ill patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016073029127N1**
Registration date: **2017-02-25, 1395/12/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-25, 1395/12/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Public funds

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of enteral Royal jelly supplementation compared to standard enteral nutrition on gut microbiota pattern and septic complication in critically ill patients

Public title

The effects of enteral Royal jelly supplementation in critically ill patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Critically ill patients aged older than 18 years and less than 65 years; at least two signs of systemic inflammatory response syndrome (body temperature above 38 C° or less than 36 C°, heart rate more than 90 min without drug interactions , respiratory rate more than 20 in minutes, WBC lees than 4000 or more than12,000 or more than 10% immature neutrophils); at least a measure organ dysfunction syndrome (oliguria acute or urine output <0.5 ml/kg/min for at least two hours despite the revival of adequate fluids, coagulation disorders) Exclusion criteria: Pregnancy and lactation; taking dose of antifungal ,catecholamine and vasopressor Drugs; Immunocompromised patients; liver failure (changes in liver enzymes more than twice normal); renal failure (serum creatinine levels> 2); gastric acidity(pH) less than 3.5

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Ethics Committee, Tehran University of Medical Sciences, Ghods St., Enghelab Sq., Tehran, Iran

City

Tehran

Postal code

-

Approval date

2016-05-29, 1395/03/09

Ethics committee reference number

IR.TUMS.REC.1395.2643

Health conditions studied

1

Description of health condition studied

Supportive care critically ill patient stay in intentensive care unit

ICD-10 code

R19.8

ICD-10 code description

Symptoms and signs involving the digestive system and abdomen

Primary outcomes

1

Description

quantitative GUT microbiota pattern

Timepoint

Baseline,3 and 7 days after intervention

Method of measurement

Extraction and purification of DNA Microbiota of fecal samples or stomach juice by using Real-time PCR and Fast Start Univesal SYBR green master with Light cycler ® 96 and draw Amplification curve

2

Description

Serum Endocan Level

Timepoint

Baseline and seventh day after intervention

Method of measurement

Serum endocan levels is measured using an endocan enzyme-linked immunosorbent assay (ELISA) kit

Secondary outcomes

1

Description
Acute Physiologic Assessment and Chronic Health Evaluation (APACHE) II Scores
Timepoint
Baseline, 3 and 7 days after intervention
Method of measurement
Standard questionnaire

Intervention groups

1

Description
Intervention group (1) patients are received an oral preparation containing 5000 mg RJ via tube feeding in addition to conventional therapy (500 kcal standard enteral nutrition therapy) per day for a week
Category
Treatment - Drugs

2

Description
Intervention group (2) (control), patients are received only conventional therapy (standard enteral nutrition 500kcal per day) for a week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mojtaba Mojtahedzadeh
Street address
Sina Hospital, Hassan Abad Sq., Imam Khomeini St., Tehran, Iran
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Mrs. Akbari
Street address
Tehran University of Medical Sciences, Ghods St., Enghelab Sq.
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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, Tehran 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

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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