

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

Name

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Name of organization / entity

Tehran University of Medical Sciences

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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 cyclcr ® 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

City

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.

City

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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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vida Kazemi

Position

Pharmacy Doctorate and PhD student

Other areas of specialty/work

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Fellowship in Critical Care, Clinical Pharmacy full professor

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Full name of responsible person

Vida Kazemi

Position

Pharmacy Doctorate and PhD student

Other areas of specialty/work**Street address**

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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