Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of processed honey and royal jelly on cancer-related fatigue: a double blind randomized clinical trial.

Protocol summary

Summary

Objectives: In this randomized double-blind placebo-controlled clinical trial we assess the effects of processed honey and royal jelly on the symptoms of CRF. Design: Processed honey and royal jelly, made under standard-state conditions with the permission of food and drug organization of ministry of health and medical education of Iran. We conducted this single center double blind randomized study between May, 2013 and August, 2014 at Shohada-e-Tajrish hospital in Tehran (Iran). In total, 52 patients were randomized into two groups: 26 participants to drug and 26 participants to placebo group. Randomization was accomplished by computer using dynamic allocation with an established algorithm that balances the marginal distribution. Fatigue was measured using a Visual Analogue Fatigue Scale (VAFS) and Fatigue Severity Scale. Inclusion criteria: age more than 18, having the diagnosis of a solid malignancy, Karnofsky Performance Status more than 70, serum hemoglobin level of more than 8g/dL, serum total bilirubin less than 2mg/dL, serum creatinine less than 2mg/dL. Intervention: Case group (26 patients) received processed honey and royal jelly, while the control group received pure honey (without royal jelly). Both groups were instructed to consume their supplement 5mL twice daily for 4 weeks. Both groups were assessd at the beginning of study, after 2 weeks, and then at the end of 4 weeks of treatment. main outcome measures: The primary outcome: changes in the fatigue severity scales

General information

Acronym

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IRCT registration information

IRCT registration number: **IRCT2015081423426N1**
Registration date: **2015-09-08, 1394/06/17**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-09-08, 1394/06/17

Registrant information

Name

Amir Shahram Yousefi Kashi

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Tehran, Iran

Country

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-03-08, 1390/12/18

Expected recruitment end date

2015-03-08, 1393/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of processed honey and royal jelly on cancer-related fatigue: a double blind randomized clinical trial.

Public title

The effect of processed honey and royal jelly on cancer-related fatigue

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age more than 18; having the diagnosis of a solid (non-hematologic) malignancy; visual analogue scale (VAS) more than 4; Karnofsky Performance Status (KPS) more than 70; serum hemoglobin level of more than 8g/dL with no abrupt decrease (more than 2g/dl) during the last month; Liver enzymes not more than three times above the normal limits; serum total bilirubin less than 2mg/dL; serum creatinine less than 2mg/dL and creatinine clearance more than 60ml/mi. Exclusion criteria: Patients with hypersensitivity to honey, uncontrolled cardiac or respiratory problems; any other serious medical condition, including severe infection or uncontrolled pain; pregnancy, major depression; taking medications with potential effects on fatigue; such as psychiatric medication (anti-depressants; psychostimulants,etc) or growth factors like erythropoietin.
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
randomization were done with using block randomization

Secondary Ids

1

Registry name
--
Secondary trial Id
--
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
2nd Shahid Beheshti University of Medical Sciences Bldg. ,Next to Ayatollah Taleghani Hospital, Evin
City
Tehran
Postal code
198396-3113
Approval date
2012-03-08, 1390/12/18
Ethics committee reference number
m269

Health conditions studied

1

Description of health condition studied
Neoplasms
ICD-10 code
C15, C16,
ICD-10 code description

Primary outcomes

1

Description
Cancer-related fatigue
Timepoint
Before intervention, 2 Weeks after intervention and 4 weeks after intervention
Method of measurement
Fatigue Severity Scale

Secondary outcomes

1

Description
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Timepoint
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Method of measurement
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Intervention groups

1

Description
Intervention group 1: 26 patients received processed honey and royal jelly. Processed honey and royal jelly, made under standard-state conditions with the permission of food and drug organization of ministry of health and medical education of Iran. The intervention group were instructed to consume their supplement 5mL twice daily for 4 weeks. They were assessd at the beginning of study, after 2 weeks, and then at the end of 4 weeks of treatment.

Category
Treatment - Drugs

2

Description
Control group : 26 patients received pure honey . Pure honey , made under standard-state conditions with the permission of food and drug organization of ministry of health and medical education of Iran. The control group were instructed to consume their supplement 5mL twice daily for 4 weeks. They were assessd at the beginning of study, after 2 weeks, and then at the end of 4 weeks of treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadai-e- Tajrish Hospital
Full name of responsible person
Amir Shahram Yousefi Kashi
Street address
Shohadaie Tajrish Hospital, Tajrish square, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bahram Mofid
Full name of responsible person
Bahram Mofid
Street address
Department of Radiation Oncology,Shohada-e-Tajrish Hospital,Tajrish square
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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
Bahram Mofid
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
Shahid Beheshti University of Medical Sciences, Tehran, Iran
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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