

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 assessed 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

Iran (Islamic Republic of)

Phone

+98 21 2271 5739

Email address

dryousefi@irimc.org

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

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Secondary trial Id

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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 assessed 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 assessed 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

City

Tehran

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

Full name of responsible person

Bahram Mofid

Position

Associate Professor of Radiation Oncology

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

Shohada-e-Tajrish Hospital, Department of Radiation Oncology

City

Tehran

Postal code**Phone**

+98 21 2272 8081

Fax

+98 21 2272 8081

Email

mofid429@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences, Tehran, Iran

Full name of responsible person

Amir Shahram Yousefi Kashi

Position

Assistant Professor of Radiation Oncology, Faculty of Medicine,

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

Shohada-e-Tajrish Hospital, Department of Radiation Oncology

City

Tehran

Postal code**Phone**

+98 21 2271 5739

Fax

+98 21 2271 5739

Email

shahpoo2002@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences, Tehran, Iran

Full name of responsible person

Amir Shahram Yousefi Kashi

Position

Assistant Professor of Radiation Oncology, Faculty of
Medicine,

Other areas of specialty/work

Street address

Department of Radiation Oncology, Shohada-e-Tajrish
Hospital,Tajrish square

City

Tehran

Postal code

Phone

+98 21 2271 5739

Fax

+98 21 2271 5739

Email

shahpoo2002@yahoo.com

Web page address

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