Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of the effect of syrup of Jollab on cancer-related fatigue in patients with breast cancer: A randomised control trial

Protocol summary

Study aim
Determination of the effect of syrup of Jollab on the fatigue of patients with breast cancer
Design
Two arm parallel group randomised clinical trial, triple blinded
Settings and conduct
Design of the study: Women patients with breast cancer referring to Shohaday-e- Tajrish Hospital of Tehran who have symptoms of cancer-related fatigue. In order to blind the investigator, medications are named as "A" for syrup of Jollab and B for placebo. The patient don't aware of the type of drug she is assigned to. In addition, the groups are entered into statistical analysis as "A" and "B
Participants/Inclusion and exclusion criteria
Inclusion criteria: women suffer from breast cancer-related fatigue; 1.Age between 18- 70 years old; 2. Hemoglobin level is at least 8g/dl; 3. Hematocrit level at least 30%; 4. normal TSH. Exclusion criteria: 1. Heart disease with unstable conditions; 2. Disabling Pulmonary Disease and History of Asthma; 3. Severe kidney disease; 4. Creatinine level greater than 2mg/dl; 5. Proteinuria; 6. The SGOT level more than 3 times of the normal threshold; 7. Bilirubin levels greater than 2mg/dl; 8. Positive history of hypersensitivity to saffron, rose water and honey; 9. severe infection; 10. Systemic disease;11. Positive history of gout or high level of uric acid; 12. An individual who uses antidepressants due to depression; 13. Simultaneous use of drugs that affect fatigue; 14. Uncontrolled pain; 15. Unwillingness to participate in the study.
Intervention groups
Group A: patients with breast cancer-related fatigue receiving syrup of Jollab, 10 cc three times daily; Group B: patients with breast cancer-related fatigue receiving placebo, 10 cc three times daily
Main outcome variables
The mean of score of "Visual Analogue Fatigue Scale", 2. The mean of score of "Fatigue Severity Scale", 3. The mean of score of "The Cancer Fatigue Scale"

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150825023753N8**
Registration date: **2018-06-05, 1397/03/15**
Registration timing: **retrospective**

Last update: **2018-06-05, 1397/03/15**
Update count: **0**
Registration date
2018-06-05, 1397/03/15

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-11-01, 1396/08/10
Expected recruitment end date
2018-05-20, 1397/02/30
Actual recruitment start date
2017-11-01, 1396/08/10
Actual recruitment end date
2018-05-20, 1397/02/30
Trial completion date

empty

Scientific title
Study of the effect of syrup of Jollab on cancer-related fatigue in patients with breast cancer: A randomised control trial

Public title
Effects of syrup of Jollab on fatigue in patients with breast cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female gender Age between 18- 70 years old Patients known case of breast cancer Hemoglobin level is at least 8 g / dl Hematocrit level at least 30% The level of TSH is normal

Exclusion criteria:
Patients known case of heart disease with unstable conditions Disabling Pulmonary Disease and History of Asthma Patients known case of severe kidney disease Creatinine level is greater than 2mg / dl Proteinuria The SGOT level is more than 3 times of the normal threshold Bilirubin levels is greater than 2mg / dl Positive history of hypersensitivity to saffron, Rose water and Honey Uncontrolled pain, severe infection, serious illness Positive history of gout or high level of uric acid An individual who uses antidepressants due to depression Simultaneous use of drugs that affect fatigue Unwillingness to participate in the study Active treatment for anemia (transfusion or Epoetin Alfa Injection)

Age
From **18 years** old to **70 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation software Ink was used to create a randomization table

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to blind the investigator, medications were named A (syrup of Jollab) and B (Placebo). The patient was not aware of the type of drug he was assigned to. The groups were also coded A and B to the statistical analyzer.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee on Biomedical Research of Shahid Beheshti University of Medical sciences

Street address
Shahid Beheshti University of Medical sciences, Daneshju Blv.

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2017-10-29, 1396/08/07

Ethics committee reference number
IR.SBMU.REC.1396.525

Health conditions studied

1

Description of health condition studied
Neoplastic (malignant) related fatigue

ICD-10 code
R53.0

ICD-10 code description
Neoplastic (malignant) related fatigue

Primary outcomes

1

Description
Score of Fatigue Severity "Visual Analogue Fatigue Scale"

Timepoint
The weeks of 0 and 4 after treatment

Method of measurement
Using Visual Analogue Fatigue Scale questionnaire

2

Description
Score of "Fatigue Severity"

Timepoint
The weeks of 0 and 4 after treatment

Method of measurement
Fatigue Severity Scale questionnaire

3

Description
Score of "The Cancer Fatigue Scale"
Timepoint
The weeks of 0 and 4 after treatment
Method of measurement
The Cancer Fatigue Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with breast cancer-related fatigue receiving syrup of Jollab, 10 cc three times daily for four weeks;
Category
Treatment - Drugs

2

Description
Control group: patients with breast cancer-related fatigue receiving placebo, 10 cc three times daily for four weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohay-e-Tahrish Hospital
Full name of responsible person
Dr. Ghazaleh Heydarirad
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Tajrish Square, Shohaday-e-Tejarish Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ghazaleh Heydarirad
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic data and the result of the clinical trial

When the data will become available and for how long
6 month later

To whom data/document is available
Researchers

Under which criteria data/document could be used
After publication of the extracted article of the clinical trial

From where data/document is obtainable
Sending Email to the researchers

What processes are involved for a request to access data/document
Sending the request via the email

Comments