# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 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**
Mohammad Mahdi Parvizi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 71 3212 5592

**Email address**
parvizim@sums.ac.ir

**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
**Street address**
Tajrish Square, Shohaday-e-Tejarish Hospital
**City**
Tehran
**Province**
Tehran
**Postal code**
1989934148
**Phone**
+98 21 2274 9201
**Email**
ghazalrad@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Dr. Ghazaleh Heydarirad
**Street address**
Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences
**City**
Tehran
**Province**
Tehran
**Postal code**
1516745811
**Phone**
+98 21 8877 6027
**Email**
ghazalrad@yahoo.com
**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**
Ph.D.
**Other areas of specialty/work**
Traditional Medicine
**Street address**
Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences
**City**
Tehran
**Province**
Tehran
**Postal code**
1516745811
**Phone**
+98 21 8877 6027
**Email**
ghazalrad@yahoo.com

## Person responsible for scientific 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**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

**Street address**
Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences

**City**
Tehran

**Province**
Tehran

**Postal code**
1516745811

**Phone**
+98 21 8877 6027

**Email**
ghazalrad@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Shiraz University of Medical Sciences

**Full name of responsible person**
Dr. Mohammad Mahdi Parvizi

**Position**
Assistant professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

**Street address**
Zand Street

**City**
Shiraz

**Province**
Fars

**Postal code**
7134844119

**Phone**
+98 71 3235 1087

**Email**
mmparvizi@gmail.com

## 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**