Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

The effect of "Maoljobon (whey)" on Cancer patients with chemotherapy_ induced "hand and foot syndrome" and their quality of life

Protocol summary

Study aim
Improving the quality of life of patients

Design
Triple blinded intervention Randomize clinical Trial -triple blinded - controlled Simple randomization of available patients Phase 3

Settings and conduct
From the hospitals and offices of oncologists in Qom, the files of all cancer patients who have sought treatment for chemotherapy drugs, including Capecitabine Dejar Syndrome, have been extracted, and eligible patients are divided into intervention and control groups. Demographic information, type and stage of cancer of patients will be recorded.

Participants/Inclusion and exclusion criteria
معیارهای ورود: تمام بیماران بالای 18 سال مبتلا به سندروم دست و پای ناشی از شیمی درمانی، از جمله داروی Capecitabine، که رضایت به شرکت در مطالعه دارند. معیارهای عدم ورود: بیماران مبتلا به دیگر ضایعات پوستی- وجود عفونت- بیماری التهابی روده- سابقه حساسیت شدیدبه شیر Inclusion criteria: All patients over 18 years of age with chemotherapy-induced hand and foot syndrome, including Capecitabine, who agree to participate in the study. Criteria for not entering: Patients with other skin lesions - Infection - Inflammatory bowel disease - History of severe milk allergy

Intervention groups
The intervention group consumes 15 grams of malt powder twice a day, in the morning and in the evening, which should be dissolved in 100 cc of lukewarm boiled water, and sip, and eat something until one hour after consumption. Do not use. Mercury will be used for 6 weeks and 2 days. At the same time, both control and intervention groups, 20% glycerin ointment; Use topically.

Main outcome variables
Common Terminology Criteria for Adverse Event, Edition 5, including the definition of three degrees of the syndrome, grades 1, 2, and 3, to assess the degree of lesion Pain rate, Evaluation of redness and scaling of skin lesions Evaluation of burning, itching and, numbness of skin lesions

General information

Reason for update

Acronym
EMCHFS

IRCT registration information
IRCT registration number: **IRCT20220317054317N1**
Registration date: **2022-04-04, 1401/01/15**
Registration timing: **prospective**

Last update: **2022-04-04, 1401/01/15**
Update count: **0**

Registration date
2022-04-04, 1401/01/15

Registrant information

Name
Akram Ashoori

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 25 3293 7569

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-05, 1401/02/15

Expected recruitment end date
2024-05-04, 1403/02/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of "Maoljobon (whey)" on Cancer patients with chemotherapy_ induced "hand and foot syndrome" and their quality of life

Public title

The effect of "Maoljobon (whey)" on Cancer patients with chemotherapy induced "hand and foot syndrome"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients over 18 years of age with hand syndrome and reason for chemotherapy, from Capecitabine, who are willing to participate in the study.

Exclusion criteria:

Patients with other skin lesions - Infection - Inflammatory bowel disease - History of severe milk allergy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first step, the groups are written as groups A and B. A lottery is then drawn between the two groups to determine which letter is in the intervention group and which is in the control group. In the second step, 60 numbers, from one to 60, are written on paper and completely closed so that they are not visible and are thrown into a container. Then, in the third step, a person will announce that the patients will choose the intervention or control group, then pick up a number from the container and read it and take notes in the group that announced it. This is done 30 times without substitution until all the people in the announced group are identified, then the remaining 30 numbers are assigned to the second group. Finally, when patients come to the clinic, each patient has a number from inside a container that contains 60 numbers from one to 60 and is written on paper and is not visible, and gives it to the therapist, then the therapist opens the number paper and Looks at the list of groups. The selected number belongs to each group. The patient is placed in that group and this is done up to 60 times to complete the groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

During the study and sampling, the therapist, researcher and patients will not know the type of group (control or intervention) and try to invite patients to visit at a distance so as not to meet each other and not be informed about the content of the treatment. The distribution of medicine according to the group list will be done by one of the staff of the center who is not involved in the examination and collection of information. After collecting the data, the analyzers will not know the patient group

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

Safashahr St., University Jihad Alley, Shahid Lotfi Niasar (Alley No. 4), No. 83

City

qom

Province

Ghoum

Postal code

3713649373

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.MUQ.REC.1400.244

Health conditions studied

1

Description of health condition studied

Chemotherapy-induced hand and foot syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain in the lesions

Timepoint

Before the intervention, one day and one week after the

intervention period

Method of measurement

visual analog scale

2

Description

Degree of waste

Timepoint

Before the intervention, one day and one week after the intervention period

Method of measurement

Common Terminology Criteria for Adverse Event

3

Description

The amount of burning and itching and numbness of the lesions

Timepoint

Before the intervention, one day and one week after the intervention period

Method of measurement

Likert Questionnaire

4

Description

Scaling rate and redness of the lesions

Timepoint

Before the intervention, one day and one week after the intervention period

Method of measurement

Dermatologist photography and opinion

Secondary outcomes

1

Description

Overall quality of life

Timepoint

before the intervention and one day and one week after the intervention period

Method of measurement

(Quality of Life)questionnaire

2

Description

Quality of life of a skin patient

Timepoint

before the intervention and one day and one week after the intervention period

Method of measurement

Dermatology Life Quality Index questionnaire

Intervention groups

1

Description

The brewery is the whey that is obtained as a by-product of cheese production, after the separation of milk casein, and contains lactose and a variety of proteins, minerals, vitamins, and fats. Depending on the type of milk and methods of this process, various products are created. In this project, among the methods of coagulation of milk in traditional medicine by vinegar, peppermint or shoe eggs, the type of peppermint has been selected. Freshly boiled milk will be cut through powdered sugar and a little vinegar. After the milk is completely cut, the container is removed from the fire. The contents of the container, which is still slightly warm, are poured into a fine-textured canvas cloth and the water is collected in a container. After collecting the liquid, it is turned into powder in the freezer and packaged Intervention group: People in the intervention group consumed 15 grams of malt powder twice a day, morning, morning, and evening, which should be dissolved in 100 ccs of lukewarm boiled water, and sip, and consumed until one hour later. Do not eat anything. The use of malt water will be for 6 weeks and 2 days. At the same time, for both control and intervention groups, 20% glycerin ointment; Use topically.After preparing the powder in one of the reputable laboratories, it is examined for fungi and microbes, and after making sure that no microbial and fungal counts have grown in the powder product, it will enter the clinical phase.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals and oncologist offices in qom

Full name of responsible person

Akram Ashoori

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Akram Ashoori
Position
Associate
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

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

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data will be sent on request by researchers.

When the data will become available and for how long

After printing the study results

To whom data/document is available

researchers

Under which criteria data/document could be used

For systematic review studies or meta-analysis

From where data/document is obtainable

Dr. Majid Asghari

What processes are involved for a request to access data/document

Correspondence by email with the project manager

Comments