Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Chamomile oil on lymphedema volume, range of motion and quality of life in breast cancer related lymphedema

Protocol summary

Study aim
Evaluation of the effect of Chamomile oil on lymphedema volume, range of motion and quality of life in breast cancer related lymphedema
Design
clinical trial-Randomized-Comparison between traditional medicine product and conventional intervention
Settings and conduct
Randomization trial for lymphedema after breast cancer by which lymphologist selected for tratment and then 3 group:1group Routinly CDT(MLD,Skin lotion,Bandajing) 2.CDT by chamomile oil(baise of olive oil) 3.CDT by olive oil Plaise of intervention:Lymphedema clinic of Motamed Cacer instiute.Tehran,Iran
Participants/Inclusion and exclusion criteria
The inclusion criteria this trial: -Age 35-75 -Lymphedema over volium betwin upper limb 200ml -History Breast Cancer -Minimum after other tretment(surgery, chemotheropy,radiotherapy) Non entry criteres: -Inflamaines -CHF -RF -Others Cancer -DVT -Metastatic Cancer
Intervention groups
Coindide interventio group: 1.Rotinly CDT 2.CDT by chamomile oil(base of olive oil 3.CDT by olive oil
Main outcome variables
Volum edema upper limb, Renge of motion shoulder,Quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190312043024N1**
Registration date: **2019-09-15, 1398/06/24**
Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **0**
Registration date
2019-09-15, 1398/06/24

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-02-04, 1397/11/15
Expected recruitment end date
2019-08-06, 1398/05/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Chamomile oil on lymphedema volume, range of motion and quality of life in breast cancer related lymphedema

Public title
Effect of Chamomile oil in breast cancer related lymphedema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Lymphedema with overvolume of 200 mililiter between two uper limbs history of breast cancer At least one month after last chemotherapy/radiotherpy and surgery Informed consent

Exclusion criteria:

acute/ chronic infection CHF RF Lymphedema post other cancer smoker or alchohol consumer DVT Metastatics patient

Age

From **35 years** old to **75 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

After registration of patients in the study according to the inclusion and exclusion criteria, they will be randomized to one af the treatment groups: group A: CDT, group B: CDT plus herbal oil and group C: CDT plus placebo. The simple randomization method was used for randomization in this study. The statistician will randomly start with a number of the random number table. According to the three groups of treatment in this study, if the random number was 1, 2 or 3 they will be assigned to the treatment group A and if: the random number was 4, 5 or 6 they will receive treatment of group B. Random numbers of 7, 8 or 9 will assign patients to the group C. This randomization will continue to the last patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Despite the statistician, patients and the lymphotherapist will be blinded to the treatment in groups B and C. for the blinding purpose, a placebo will be used which is similar with the herbal oil in the case of color, appearance, and smell. lymphotherapist, will have a list and when a patient comes to the clinic its name will be signed up on the list. Then the statistician will be informed by a phone call of the new patient and will randomize the patient to one of the treatment groups. The statistician will bring the oil/placebo container (which is same for bothherbal oil and placebo) and will write the name of the patient on it so the lymph therapist will be blind to the treatment group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Research Ethics Committee.

Street address

Simay-e Iran Ave

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1985717443

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1195

Health conditions studied

1

Description of health condition studied

Lymphedema

ICD-10 code

I97.2

ICD-10 code description

Postmastectomy lymphedema syndrome

Primary outcomes

1

Description

lymphedema volume-RoM(renge of motion)

Timepoint

setion 0(befor treatment)-7-14-21 and 1month after treatment

Method of measurement

measuring using water displacement by cylinder and Goniometr

2

Description

Qouality of life

Timepoint

setion 0(befor treatment)- setion21(aftet treatment) and 1month after treatment

Method of measurement

Short form health survey(SF 36) Quesionary

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: CDT by Chamomile oil base of olive. CDT is the conventional management for lymphedema which includes maneuvers, bandaging, skincare and education of patient on these procedures. Before the bandaging, the lymphedematous limb should be washed with children lotion (firooz) but at this intervention herbal oil will be used. 75 ccs for each lymphedematous limb. Bandages are Germany products (AtaTeb Novin). The herbal oil was produced by pharmacists in the Department of Traditional Medicine, School of Traditional Medicine, University of Shahid Beheshti. The intervention period is 21 sessions and will be performed continuously except on Thursdays and Fridays.

Category
Treatment - Drugs

2

Description
Intervention: CDT plus placebo (base oil of olive) Same as the previous intervention, except in this group only olive oil will be used before the bandaging.

Category
Treatment - Drugs

3

Description
Control group: rutin CDT(MLD+ Bandaging+Skin care)

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Motamed Cancer Institute

Full name of responsible person
Zahra sheikhiMobarakeh

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Sponsors / Funding sources

1

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mmotamed cancrer inistitiut

Proportion provided by this source
30

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
Zahra SheikhiMobarakeh

Position
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Latest degree
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Publishing resultin from of PhD thesis an article indexing ISI
When the data will become available and for how long
after PhD thesis defence
To whom data/document is available
Publitic
Under which criteria data/document could be used
For Researchers
From where data/document is obtainable
Dr zahra sheikhi,Motamed Cancer Center
What processes are involved for a request to access data/document
Approving by responsible officer
Comments