

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Survey the effect of topical heparin gel on the improvement of hand and foot syndrome in cancer patients treated with capecitabine

Protocol summary

Study aim

the effect of topical heparin gel in improving hand and foot syndrome in patients use capecitabine

Design

40 patients are divided into two groups of 20 by simple randomization method, so that the envelopes containing cards A and B will be randomly distributed among the patients. Group A as the intervention group, in addition to standard chemotherapy treatment, will receive heparin sulfate gel 40 mg 4 times a day for 21 days, and group B as the control group will only receive standard treatment and placebo gel. All patients were included in the study before starting cancer treatment with capecitabine. The start of the study coincided with the start of cancer treatment. This study will be conducted in a double-blind manner, so that neither the patient nor the researcher will be aware of the type of intervention.

Settings and conduct

In this clinical trial study, 40 patients who are in the oncology department of Kashani and Hajar Hospital with hand and foot syndrome grade less than 2, age 18 years or older, and in the study by randomization method. They are simply divided into two groups of 20 so that envelopes containing cards A and B will be randomly distributed among the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Newly diagnosed cancer patients for gastrointestinal and head and neck cancer treated with capecitabine Have the initial symptoms of hand and foot syndrome Non-entry criteria: The patient already has a skin or inflammatory disease

Intervention groups

intervention group A, in addition to standard chemotherapy treatment, will receive heparin sulfate gel 40 mg 4 times a day for 21 days, control group B will only receive standard treatment and placebo gel.

Main outcome variables

The amount of erythema, blisters and hyperkeratosis of hand and foot syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230215057423N1**

Registration date: **2023-05-01, 1402/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-01, 1402/02/11**

Update count: **0**

Registration date

2023-05-01, 1402/02/11

Registrant information

Name

Maede Mirjalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

st_mirjalilim@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-11-01, 1402/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

	Survey the effect of topical heparin gel on the improvement of hand and foot syndrome in cancer patients treated with capecitabine
Public title	The effect of heparin gel in improving hand and foot syndrome in patients treated with capecitabine
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Newly diagnosed cancer patients for gastrointestinal tract and head and neck cancer treated with capecitabine and have evidence of early onset of hand-foot syndrome (grade 1 from onset)
Exclusion criteria:	The patient already has a skin or inflammatory disease The patient's unwillingness to start the trial
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Randomized
Randomization description	In order to randomize, the permutation block randomization method will be used. 7 blocks with a volume of 6 will be produced by RA software, each block will contain 3 letters A and 3 letters B.
Blinding (investigator's opinion)	Double blinded
Blinding description	This study will be conducted in a double-blind manner, so that neither the patient nor the researcher is aware of the type of intervention. The placebo gel will be designed with a packaging and appearance completely similar to heparin gel and will be provided to the researcher in the form of coding. The researcher is also unaware of the contents of the packaging. As a result, the data will be collected and provided to the analyst. In order to randomize, the permutation block randomization method will be used. 7 blocks with a volume of 6 will be produced by RA software, each block will contain 3 letters A and 3 letters B.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics Committee of Shahrekord University of Medical Sciences
Street address	Parastar street Hajarhaspatal
City	Shahrekord
Province	Chahar-Mahal-va-Bakhtiari
Postal code	8813833435
Approval date	2022-09-14, 1401/06/23
Ethics committee reference number	IR.SKUMS.MED.REC.1401.045
Health conditions studied	
1	
Description of health condition studied	cancer patient
ICD-10 code	C49.0
ICD-10 code description	Malignant neoplasm of connective and soft tissue of head, face and neck
Primary outcomes	
1	
Description	Examination of erythema, blisters and hyperkeratosis in hand and foot syndrome
Timepoint	Day zero and day twenty one
Method of measurement	Questionnaire and observation
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: Intervention group: Group A as the intervention group, in addition to the standard chemotherapy treatment, will receive heparin sulfate gel 40 mg 4 times a day for 21 days.
Category	Treatment - Drugs

2

Description

Control group: Control group: Group B as a control group, in addition to the standard treatment, receive a placebo that looks like heparin gel.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar and Kashani hospitals in Shahrekord

Full name of responsible person

Ruhollah Masoumi

Street address

parastar street Hajar Hospital

City

Shahrekord

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Chahar-Mahal-va-Bakhtiari

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8813833435

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+98 38 3222 0016

Email

masomi51@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Ruhollah Masoumi

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Maede Mirjalili

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Ruhollah Masoumi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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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

To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address maedemirjalili98@gmail.com or the contact number 00989132736651.

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments