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 Hajarhaspital
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 Haspital
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Phone
+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
Street address
Parastar street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Phone
+98 38 3222 0016
Email
masomi51@gmail.com
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
Street address
Parastar
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Phone
+98 38 3222 0016
Email
maedemirjalili98@gmail.com

Person responsible for scientific 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
Street address
Parastar
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Phone
+98 38 3222 0016
Email
maedemirjalili98@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Ruhollah Masoumi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

Street address
Parastar

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813833435

Phone
+98 38 3222 0016

Email
masomi51@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
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