Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Formulation and clinical assessment of erythropoietin oral gel in treatment of stomatitis caused by chemotherapy: A double blind clinical trial

Protocol summary

Study aim
Formulation and clinical assessment of erythropoietin oral gel in treatment of stomatitis caused by chemotherapy

Design
Randomized clinical trial with 2 parallel blinded groups ,on 50 patient ,Randomized block method of random replacement price by RA software

Settings and conduct
After preparing honey and erythropoietin, the preparation of a combined formulation is done in the form of 6000 units of erythropoietin in 100 grams of honey. He puts it in the mouth that has symptoms (10 grams per day). The patients were divided into two groups of 25 people, respectively: the first group: routine drugs plus honey as a gel base, and the second group: routine drugs plus oral gel (varitropoietin honey). And the first, seventh, and fourteenth days are examined and recorded in the relevant checklist. The results are analyzed using spss software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who receive chemotherapy for solid tumors or hematology and the treatment regimen is capable of causing mucositis, having consent to participate in the study, having neutrophils between 1800 and 7700 per cubic millimeter, age 14 to 60 years, exclusion criteria : having diabetes, kidney disease, liver disease, digestive diseases, allergy, allergic rhinitis, asthma, having immune system deficiency disease, history of smoking, hookah, tobacco, drugs and alcohol, receiving radiation therapy for one hour, Death or non-cooperation of patients.

Intervention groups
One group uses routine drugs along with honey gel and one group uses routine drugs along with honey gel and erythropoietin.

Main outcome variables
In case of favorable therapeutic effects, this compound can be effective in oral lesions caused by chemotherapy.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240723062520N1**
Registration date: **2024-08-01, 1403/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-01, 1403/05/11**
Update count: **0**

Registration date
2024-08-01, 1403/05/11

Registrant information

Name
Seyedeh Fatemeh Abedi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3774 7456

Email address
st_abedi@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-31, 1403/05/10

Expected recruitment end date
2024-09-07, 1403/06/17

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and clinical assessment of erythropoietin oral gel in treatment of stomatitis caused by chemotherapy: A double blind clinical trial

Public title

Formulation and clinical assessment of erythropoietin oral gel in treatment of stomatitis caused by chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who receive chemotherapy for solid tumor or hematology and the treatment regimen is capable of causing mucositis. Having neutrophils between 1800 and 7700 per cubic millimeter Being 14 to 60 years old

Exclusion criteria:

Having an underlying disease of diabetes, kidney disease, liver disease, digestive diseases, allergy, allergic rhinitis, asthma, having an immune system deficiency disease History of smoking, hookah, tobacco, drugs and alcohol, receiving radiation therapy for one hour Death or non-cooperation of patients

Age

From **14 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Replacement blocks - 5 blocks with a volume of 10 were prepared with RA software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in the research plan and their companions - the student who is the main researcher, data collector and outcome evaluator - the consultant professor and the hospital staff who are the clinical care of the patients - the statistical consultant who analyzes the data .

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

No. B46 ,5 Alley, North Mushfegh Kashani Ave

City

Isfahan

Province

Isfehan

Postal code

8179697394

Approval date

2024-07-03, 1403/04/13

Ethics committee reference number

IR.SKUMS.MED.REC.1403.052

Health conditions studied

1

Description of health condition studied

oral mucositis

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

Primary outcomes

1

Description

Age

Timepoint

before starting treatment

Method of measurement

Birth certificate age

2

Description

Treated groups

Timepoint

before starting treatment

Method of measurement

observation

3

Description

Erythema and pain

Timepoint

Days 1,7,14

Method of measurement
observation

4

Description
Erythema and ulcer
Timepoint
Days 1,7,14
Method of measurement
observation

5

Description
Severe Erythema and ulcer
Timepoint
Days 1,7,14
Method of measurement
observation

6

Description
Severe stomatitis without the ability to eat
Timepoint
Days 1,7,14
Method of measurement
observation

7

Description
type of medicine
Timepoint
Days 1,7,14
Method of measurement
observation

8

Description
Duration of illness
Timepoint
Days 1,7,14
Method of measurement
observation

9

Description
The number of neutrophils
Timepoint
After the first course of chemotherapy
Method of measurement
Complete blood count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The combined formulation is prepared in the form of 6000 units of erythropoietin in 100 grams of honey (as a gel base), the patient takes a specific amount of the medicine with a special measuring cup and puts it on any part of the mouth that has symptoms (10 grams per day). . - The amount of medicine that reaches the oral mucosa is 60 units per 10 grams of medicine, in this group of patients, they receive routine medicines along with erythropoietin honey gel for 14 days and three times a day.
Category
Treatment - Drugs

2

Description
Control group: patients in this group receive honey gel (placebo), the total amount of placebo is 100 grams. In this group, patients receive routine medications with honey gel for 14 days and three times a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital
Full name of responsible person
Ruhollah Masoumi
Street address
Between 43 and 45 alley, Nurse street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816854633
Phone
+98 38 3222 5505
Email
Hajar-Hospital@SKUMS.ac.ir

2

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Ruhollah Masoumi
Street address
Between 44 and 46 alley, Nurse street
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Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816758915

Phone
+98 38 3226 4825
Email
Kashani@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Kourosh Shakarian
Street address
Ayatollah Kashani Boulevard, Shahrekord University of Medical Sciences
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3333 0061
Email
info@skums.ac.ir
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
Seyedeh Fatemeh Abedi
Position
Dental student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No. 5, 5 Alley, North Mushfegh Kashani Ave
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Isfehan
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Email
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Person responsible for scientific inquiries

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Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Seyedeh Fatemeh Abedi
Position
Dental student
Latest degree
A Level or less
Other areas of specialty/work
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Street address
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Isfehan
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Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Seyedeh Fatemeh Abedi
Position
Dental student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No. 46 ,5 Alley, North Mushfegh Kashani Ave
City
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Postal code
8179697394
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+98 31 3774 7456
Email
st_abedi@skums.ac.ir

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
Patients' information such as age, gender, type of illness, medications, etc., which are given in the relevant checklist, can be shared.

When the data will become available and for how long
From 2024

To whom data/document is available
Researchers working in academic and pharmaceutical institutions

Under which criteria data/document could be used
Researchers working in academic and pharmaceutical institutions

From where data/document is obtainable
Seyedeh Fatemeh Abedi sfa1376@gmail.com st_abedi@skums.ac.ir

What processes are involved for a request to access data/document
2-3 weeks is the time required to share the information of this study with the document requester.

Comments