Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Determining the effects of mouthwash from areal parts Alhagi sp. aerial parts extract on paraquat-induced oral ulcers in poisoned patients

Protocol summary

Study aim
Determining the effects of mouthwash from areal parts Alhagi sp. aerial parts extract on paraquat-induced oral ulcers in poisoned patients

Design
This clinical trial does not have a control group that will be performed on 45 patients. Patients will be randomly divided into three groups of 15 based on a random number table and will be treated without blinding.

Settings and conduct
This study is an interventional and clinical trial that will be performed on 45 poisoned people referred to the poisoning ward of Afzalipour Hospital in Kerman. Given that three groups of 15 people receive standard treatment.

Participants/Inclusion and exclusion criteria
Inclusion conditions include definitive use of paraquat herbicide with toxic dose and patients 'consent to participate in the study and non-entry conditions include poisoning with other herbicides other than paraquat, non-toxic dose of paraquat, patients' lack of cooperation due to oral ulcers, patient dissatisfaction To participate in the study.

Intervention groups
There are three intervention groups: one group with triamcinolone paste (given 3 times a day every 8 hours for a month) and the second group with mouthwash obtained from the combination of aluminum hydroxide + lidocaine + diphenhydramine and the third group with mouthwash containing 0.1 extract. Percentage of Alhagi plant (10 cc of it is given to each person in 3 times every 8 hours for one month) will be treated and examined in order to heal oral ulcers caused by paraquat poisoning.

Main outcome variables
Seven variables are examined during the treatment process: 1. Oral lesions 2. Difficulty in eating food due to its consistency 3. Difficulty in speaking 4. Discomfort while moving the mouth 5. Difficulty in swallowing 6. The number of areas involved in the oral cavity 7. intensity of pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220515054856N1**
Registration date: **2022-07-23, 1401/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-23, 1401/05/01**
Update count: **0**

Registration date
2022-07-23, 1401/05/01

Registrant information
Name
Faranak Nasiri Majd
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-06-22, 1401/04/01
Expected recruitment end date
2023-06-22, 1402/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Determining the effects of mouthwash from areal parts Alhagi sp. aerial parts extract on paraquat-induced oral ulcers in poisoned patients

Public title
Determining the effects of mouthwash from areal parts Alhagi sp. aerial parts extract on paraquat-induced oral ulcers in poisoned patients

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive use of paraquat herbicide with toxic dose (based on history, clinical examination, endoscopic findings) Patient consent to participate in the study

Exclusion criteria:
Poisoning with other herbicides other than paraquat (based on history, clinical examination, endoscopic findings) Non-toxic dose of paraquat (endoscopy and normal tests) Patient dissatisfaction to participate in the study Patients do not cooperate to take medicine due to mouth ulcers

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of the unit is done by block method with a block size of 4. For each of the 6 possible states for the quadruple block, the numbers are assigned as follows: ABBA (3), ABAB (2), AABB (1), BAAB (6), BABA (5), BBAA (4) using the table Random numbers, numbers between 1 and 6 are selected and the treatment allocation list is specified according to each number. To execute the generated random sequence, the method of hiding encoded boxes or cans is used. In this method, the cans are numbered according to a random sequence and inside the boxes, the desired intervention (drug) or a sheet on which the random allocation is written, is provided to the executor with the condition that the boxes are completely sealed and The researcher assigns patients to the standard intervention and treatment group based on the order of patients' admission. Tools: Creating a random sequence of 4 hiding random blocks to execute a random sequence on study participants. How to build: Randomly select the block and read the letters from right to left. The cans are the same weight and shape and will be prepared by an independent researcher.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
The beginning of Haft Bagh Alavi axis, campus of University of Medical Sciences

City
kerman

Province
Kerman

Postal code
7616913555

Approval date
2022-06-12, 1401/03/22

Ethics committee reference number
IR.KMU.REC.1401.090

Health conditions studied

1

Description of health condition studied
Paraquat herbicide poisoning

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The rate of change (decrease or increase) in the size of oral lesions

Timepoint
3, 7 and 30 days after patient visit and discharge time

Method of measurement
Pemphigus Oral Lesions Intensity Score (POLIS) Questionnaire

2

Description
Evaluation of difficulty in eating due to its consistency

Timepoint
At the beginning of the study (before the intervention) and 3, 7 and 30 days after the patient's visit and

discharge time

Method of measurement

Pemphigus Oral Lesions Intensity Score (POLIS) Questionnaire

3

Description

Check the Speech Problem

Timepoint

At the beginning of the study (before the intervention) and 3, 7 and 30 days after the patient's visit and discharge time

Method of measurement

Pemphigus Oral Lesions Intensity Score (POLIS) Questionnaire

4

Description

Check for discomfort when opening and moving the mouth

Timepoint

At the beginning of the study (before the intervention) and 3, 7 and 30 days after the patient's visit and discharge time

Method of measurement

Pemphigus Oral Lesions Intensity Score (POLIS) Questionnaire

5

Description

Check for swallowing problems

Timepoint

At the beginning of the study (before the intervention) and 3, 7 and 30 days after the patient's visit and discharge time

Method of measurement

Pemphigus Oral Lesions Intensity Score (POLIS) Questionnaire

6

Description

Check the number of areas involved in the oral cavity

Timepoint

At the beginning of the study (before the intervention) and 3, 7 and 30 days after the patient's visit and discharge time

Method of measurement

Pemphigus Oral Lesions Intensity Score (POLIS) Questionnaire

7

Description

Measuring pain intensity

Timepoint

At the beginning of the study (before the intervention) and 3, 7 and 30 days after the patient's visit and discharge time

Method of measurement

Questionnaire,The Numeric Pain Rating Scale (NPRS)

8

Description

Recovery time

Timepoint

From the beginning until the recovery every 4 days

Method of measurement

follow up(Examining the patient and asking the patient)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: Triamcinolone paste (made in Iran, manufacturer: Emad Darman Pars Chemical formula: C21H27FO6) which is given to the patient 3 times a day (every 8 hours) every day for a month to cover the wound surface.

Category

Treatment - Drugs

2

Description

The second intervention group : Aluminum hydroxide mouthwash + lidocaine + diphenhydramine (made in Iran, manufacturer: Iran Hormone), each person is given 10 cc 3 times a day for one month (once every 8 hours).

Category

Treatment - Drugs

3

Description

The third intervention group: Alhagi mouthwash (containing 0.1% of Kharshtar plant extract, made in the laboratory of the Faculty of Pharmacy of Kerman University of Medical Sciences) which is given to each person 3 times a day(once every 8 hours) for one month,amount of 10 CC is given from it.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital, Kerman

Full name of responsible person

Faranak Nasiri Majd

Street address

Imam Khomeini Highway, next to Shahid Bahonar University, Afzalipour Educational and Medical Center

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Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Reza Malekpour Afshar
Street address
Kerman, the beginning of Haft Bagh Alavi axis, campus of University of Medical Sciences
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Email
r_malekpoor@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Kerman University of Medical Sciences
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Toxicology
Street address
Kerman, the beginning of Haft Bagh Alavi axis, campus of University of Medical Sciences
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Faranak Nasiri Majd
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Person responsible for updating data

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Full name of responsible person
Faranak Nasiri Majd
Position
student
Latest degree

Bachelor

Other areas of specialty/work

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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

Total data

When the data will become available and for how long

Starting from 6 months after the publication of the article

To whom data/document is available

Researchers, students and doctors

Under which criteria data/document could be used

To conduct a clinical trial

From where data/document is obtainable

General or scientific responsible person

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

Send the proposal to the email of the person in charge

Comments