

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effectiveness of Arnebia euchroma Ointment and Phenytoin Cream 1% in Pressure Ulcer in patients with Spinal Cord Injury: A randomized clinical trial

Protocol summary

Study aim

Evaluation of the efficacy of topical Arnebia Euchroma ointment on Pressure ulcer

Design

Two arm parallel group randomized clinical trial, Triple blinded, 80 patients

Settings and conduct

Among the referrals to Ahwaz Welfare Services Clinic, 80 patients with Pressure ulcer that have met the inclusion criteria, are chosen by a doctor. The personal and medical information questionnaire is completed for each patient and the lesions number and wound grade are determined by the researcher in each patient (Based on pressure ulcer staging protocol table NPUAP). Then patients (with grade 2 and 3 ulcer) are randomly divided into two groups, and for a period of 5 weeks, Intervention group is applied topical Arnebia Euchroma ointment and Control group is applied Phenytoin cream 1% on Pressure ulcer twice daily. Both groups receive wound care training (Washing with normal saline, change position at least every 1 hour, Learning how to help the patient move to reduce shearing forces & friction, Use wavy mattresses on the bed, Wheelchair Inflatable Mattress). Patients will be examined during this time at one week intervals and the wound healing measurement is based on the Protocol of Pressure Ulcer Scale for Healing tool (PUSH Tool).

Participants/Inclusion and exclusion criteria

People with spinal cord injuries with pressure ulcers; Age 15 to 75 years; Necessary Cooperation in drug use; Grade 2 and 3 Wounds; Having one or more pressure ulcer; The largest wound diameter is less than 15 cm; Written informed consent; Possible follow up

Intervention groups

Intervention group: are applying Arnebia Euchroma ointment on ulcer twice daily for 5 weeks. Both groups receive wound care training. Control group: are applying

Phenytoin cream 1% on ulcer twice daily for 5 weeks.

Main outcome variables

ulcer stage; size; exudate; Pressure ulcer scale for Healing; Time of ulcer Healing.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190907044714N1**

Registration date: **2020-01-06, 1398/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-06, 1398/10/16**

Update count: **0**

Registration date

2020-01-06, 1398/10/16

Registrant information

Name

Sakineh Erabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7742 4290

Email address

erabi.s@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-06, 1398/08/15

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision of the Effectiveness of Arnebia euchroma Ointment and Phenytoin Cream 1% in Pressure Ulcer in patients with Spinal Cord Injury: A randomized clinical trial

Public title
Arnebia euchroma in treatment of Bed Sore

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient's age 15 to 75 years Necessary Cooperation in drug use Grade 2 and 3 Wounds Having one or more pressure ulcer The largest wound diameter is less than 15 cm Written informed consent Possible follow up
Exclusion criteria:
Using another drug that interferes with the effect of the drug being studied; Chronic disease (kidney leading to dialysis, kidney failure, liver, history of drug allergy); Infected wound (such as : pus, bloody discharge, bad odor, fever, ...); Having any chronic skin ulcer or another type of skin ulcer; Allergic symptoms during Arnebia euchroma Ointment testing; pregnancy

Age
From **15 years** old to **75 years** old

Gender
Both

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: **80**
More than 1 sample in each individual
Number of samples in each individual: **1**
Grade 2 or 3 non-infectious wounds less than 15 cm in diameter

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified randomization is used. Patients are divided into two groups of grade 2 and 3 according to the degree of wound and then each category randomized with using a randomized list. The block randomization method is used to make a random list. 4 member blocks made then they are selected using a random number table. The randomization list is compiled by a professor of statistics and the doctor will refer the selected patients to the nurse responsible for deliver the medication. This nurse

is not involved in other stages of treatment, review of treatment progress, and evaluations. The drugs are delivered to both groups in the same package and color.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The participant and clinical caregiver and principal investigator, and the dressing nurse and data evaluator doctor are not aware from the type of drug used. Initially it is explained to the patients that they are randomly assigned to one of two treatment groups. The drugs of both groups are synchronized and it's delivered in similar packages.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

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

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2019-08-31, 1398/06/09

Ethics committee reference number
IR.IUMS.REC.1398.560

Health conditions studied

1

Description of health condition studied
Pressure ulcer (Bed sore)

ICD-10 code
L89

ICD-10 code description
Decubitus ulcer and pressure area

Primary outcomes

1

Description
Pressure ulcer stage (Depending on the size, depth of involvement, amount of exudate, presence or absence of

infection and involvement of bone or muscle, degree of wound)

Timepoint

Day 0,7,14,21,28,35

Method of measurement

Measurement and observation

2

Description

Pressure ulcer size

Timepoint

Day 0,7,14,21,28,35

Method of measurement

Measurement and observation(Wound area cm2)

3

Description

Pressure ulcer exudate

Timepoint

Day 0,7,14,21,28,35

Method of measurement

observation

4

Description

Wound healing

Timepoint

Day 7,14,21,28,35

Method of measurement

The amount of recovery is determined by measuring the amount of exudate and color change and edema and induration is formed around the wound and granulation or epithelial tissue in the wound(Measurement and observation)

5

Description

Time to wound healing

Timepoint

Day 7,14,21,28,35

Method of measurement

observation

6

Description

Side effect

Timepoint

Day 7,14,21,28,35

Method of measurement

Question

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily wound wash with normal saline serum and Wound dressing with topical Arnebia euchroma ointment, twice daily, for 5 weeks

Category

Treatment - Drugs

2

Description

Control group: Daily wound wash with normal saline serum and Wound dressing with topical Phenytoin cream 1% Medifarm, twice daily, for 5 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Orchide rehabilitation Service Center

Full name of responsible person

Sakineh Erabi

Street address

No. 80. west 28th kianabad street, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6144965965

Phone

+98 61 3377 6479

Fax

Email

sakineh.erabi@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Abbas Motevalian

Street address

Deputy of research and technology, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Fax**Email**

research@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Sakineh Erabi

Position

MD, PHD Student of Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Behesht Street, Vahdat Slami Avenue

City

Tehran

Province

Tehran

Postal code

...

Phone

+98 21 5563 9724

Email

sakineh.erabi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Sakineh Erabi

Position

MD, PHD of Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Behesht Street, Vahdat eslami Avenue

City

Tehran

Province

Tehran

Postal code

..

Phone

+98 21 5563 9724

Email

sakineh.erabi@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Sakineh Erabi

Position

MD, PHD of Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Behesht Street, Vahdat eslami Avenue

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Tehran

Province

Tehran

Postal code

..

Phone

+98 21 5563 9724

Email

sakineh.erabi@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available