# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## 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

## 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 maked 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**

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**City**

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**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