Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of oral Mellis officinalis on serum oxidative stress and second degree wound healing

Protocol summary

Summary

This study is a clinical trial. Sixty patients with second degree burn that are hospitalized at the Burn Unit of Hazrat Vali-Asr Hospital of Arak, Iran will be recruited. After signing the study informed consent and completing the study questionnaire (for assessing information on their injury and burn, the demographic specifications and economical-social status), the patients are are randomly allocated in the two groups of intervention (30 patients) and control (30 persons). In the beginning of the study, the wound status of the patients is assessed by the researcher by Bates-Jenson standard tool and the information on oxidative stress of the patient prior to intervention is collected by taking venous blood specimen which is usually prepared for routine tests. The blood specimen of patients is centrifuged and its serum is stored in -70 centigrade degree temperature. In addition to the ordinary treatment the participants receive in burn unit, the non-fast patients in intervention group, receive 100 cc liquids made of 3 grams lemon balm leaves drink prepared in 200 cc boiled water as left for 10 minutes to be brewed, twice a day in morning and evening between two meals for two weeks period. (The leave is brewed on indirect flame by a trained person). At the end of the first and second week, the wound situation is assessed again by researcher in both intervention and control groups by using the relevant tools. The information on oxidative stress level of the patients is determined by taking venous blood specimen after intervention in both intervention and control groups. The parameters on the status of the wound and oxidative stress are analyzed by statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012312246N1**
Registration date: **2013-02-24, 1391/12/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-24, 1391/12/06

Registrant information

Name
Masumeh Abbasdust Arbastan
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8840 3119
Email address
m.abbasdost@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2012-12-10, 1391/09/20

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral Mellis officinalis on serum oxidative stress and second degree wound healing

Public title

Effect of Mellis officinalis on serum oxidative stress and

second degree wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having burn between 15 to 50 percent of body surface; having age range from 18 to 15 years old; hospitalization in burn unit; non-fasting; not having underlying diseases such as thyroid disorders, diabetics, cancer or infectious diseases; no records of drugs abuse (alcohol, narcotic drugs, under treatment with sedatives and anti-depressants); volunteered to participate in the survey; not pregnant; no records of taking supplementary antioxidants and the burn is not caused by electricity (electric devices). Exclusion criteria: refraining from continuing participation in the study; possible allergy to lemon balm; patient's discharge; transfer to another center and death of the patient.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

school of nursing and Midwifery

City

arak

Postal code

Approval date

2012-11-26, 1391/09/06

Ethics committee reference number

91-137-10

Health conditions studied

1

Description of health condition studied

Second-degree burn

ICD-10 code

T29.2

ICD-10 code description

Burns of multiple regions, no more than second-degree burns mentioned

Primary outcomes

1

Description

burning wound healing

Timepoint

Baseline - the seventh day - the fifteenth day of the intervention

Method of measurement

bates-jensenWound assessment tool

2

Description

serum antioxidant levels

Timepoint

Baseline (pre-intervention) and the end of the intervention (the fifteenth day

Method of measurement

Tests measuring levels of serum antioxidants

Secondary outcomes

1

Description

Burned Wound pain

Timepoint

Baseline - the seventh day - the fifteenth day

Method of measurement

Numerical scale of 0-10

Intervention groups

1

Description

An infusion of lemon balm herb in the intervention group, 1.5 grams 1.5 grams 9 am to 9 pm Duration of intervention: 14 days. 5 ml venous blood (blood samples routinely taken from patients) in the first and fifteenth day is taken and serum antioxidant levels are measured .A second degree burn wound in the first and seventh and fifteenth days of the bats - Jensen tools are classified scored

Category

Treatment - Drugs

2

Description
No intervention is used in control groupe . A venous blood sample (5 ml) on the first and fifteenth day of the study is to measure serum antioxidant levels occurs., A second-degree burn wound in the first and seventh and fifteenth days of the bats tools - Jensen scores are classified.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hospital of Arak

Full name of responsible person
Miss Adam pira

Street address
Valiasr square, Arak

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Davood Hekmat Pou,- PhD Nursing - Surgery - Faculty - Director of Research and Information

Street address
Director of Research and Information,pardis building,basij square,sardasht,arak

City
Arak

Grant name
17500000ریال-شماره 840-به صورت پیمانی

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Masumeh Abbasdust Aarbastan

Position
Master student of critical care nursing

Other areas of specialty/work

Street address
School of Nursing and Midwifery, Pardis building, Basij square, sardasht

City
Arak

Postal code
3848176941

Phone
+98 21 8840 3119

Fax

Email
m.abbasdost@arakmu.ac.ir; m.abasdust@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Kobra Rahzani

Position
Academic Staff - PhD Nursing - Surgical

Other areas of specialty/work

Street address
school of nursing and midwifery

City
Arak

Postal code
3848176941

Phone
+98 86 1417 3502

Fax
+98 41 73639

Email
k.rahzani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Masumeh Abbasdust Arbastan

Position
Master student of critical care nursing

Other areas of specialty/work

Street address
School of Nursing and Midwifery, Pardis building,Sardasht , Arak

City
Arak
Postal code
Phone
+98 21 8840 3119
Fax
Email
m.abbasdost@arakmu.ac.ir; m.abasdust@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty