Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical study of healing effect of topical green tea polyphenols ointment on the second degree burn wounds in patients referred to Taleghani Burn Hospital in Ahvaz

Protocol summary

Study aim

Comparison of the percentage of reduction of burn surface area, disappearance of irritation and pain on 3rd, 5th, 7th and 15th day after initiation of treatment with green tea extract cream in intervention group and control silver sulfadiazine cream treated group

Design

This is a double blind parallel clinical trial in which the physicians, the nurses and patients are unaware of the given treatment. The patients will be randomly allocated in two parallel groups with 25 patients in each one. Randomized allocation will be based on computer-generated number.

Settings and conduct

Taleghani Burn Hospital is the place for conducting the research project. Protocol: In the intervention group the burn area will be washed with sterile normal saline and a layer of polyphenol green tea cream will be applied and dressing with sterilized gauze and bandage. In the control group: The burn area will be washed with sterile normal saline and a layer of silversulfadiazine cream is applied and will be dressed with sterilized gauze and bandaged

Participants/Inclusion and exclusion criteria

Inclusion criteria: A second degree burn wound verified by the physician; Patients age between 10 to 60 years; Burn wound area less than 15% of total body surface; The time of burn incidence less than 6 hours before starting treatment; Patients with normal range of hemoglobin and total serum protein; No applied medication to the burn wound except for tap water.

Intervention groups

control group: silver sulfadiazine 1 time per day for 14 days intervention group: polyphenol of green tea formulation 1 times per day for 14 days

Main outcome variables

determination of Bets-Jensen score of burn surface area on the 3rd 5th 7th and 15th day compared to initial day in control and intervention group

General information

Reason for update

1) complete IRCT registration is mandatory before the commencement of clinical trial and recruitment of patients. Due to unforeseen circumstances which the researcher faced unexpectedly in final acceptance of IRCT process, the actual start date of the patient recruitment was different from expected commencement date. I have received the introduction letter from university on 2019/4/16 after the ethical committee and IRCT acceptance . before this date (without introduction letter) the researcher didn't had permission to present in the hospital. By this letter I was officially allowed to work in the hospital and I started my patient recruitment on the same date. This letter can be verified from research deputy of Ahvaz Jundishapur university by using the number 183/D/20/8/P . 2) To confirm the validity of the results and statistical calculations obtained by the static specialist the number of patients were increased from 30 to 50 and age range from 10 to 60.

Acronym

IRCT registration information

IRCT registration number: **IRCT20111105008013N7**
Registration date: **2019-02-16, 1397/11/27**
Registration timing: **prospective**

Last update: **2021-11-03, 1400/08/12**
Update count: **1**

Registration date

2019-02-16, 1397/11/27

Registrant information

Name

Amir Siahpoosh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 61 3334 2197

Email address
siahpoosh-a@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-04, 1397/10/14

Expected recruitment end date
2019-04-03, 1398/01/14

Actual recruitment start date
2019-04-16, 1398/01/27

Actual recruitment end date
2019-08-20, 1398/05/29

Trial completion date
2019-09-20, 1398/06/29

Scientific title
Clinical study of healing effect of topical green tea polyphenols ointment on the second degree burn wounds in patients referred to Taleghani Burn Hospital in Ahvaz

Public title
effect of Grean tea on burn wounds

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
A second degree burn wound verified by the physician Burn wound area should be less than 15% of total body surface The time of burn incidence should be less than 6 hours before starting treatment The patients should have normal range of hemoglobin and total serum protein No medication except tap water should have been applied to the burn wound

Exclusion criteria:
wounds contaminated with excess materials patients taking immune suppressive drugs such as corticosteroids , chemotheraputic drugs or undergoing radiation therapy patients suffering from immune deficiency-associated diseases such as diabetes, cancer, or any metabolic disease. patients suffering from any symptomatic infection

Age
From **10 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **30**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization with quadruple blocks. blocks are produced by use of the online site (www.sealedenvelope.com).

Blinding (investigator's opinion)
Double blinded

Blinding description
Unique codes for each patient, generated by the software, will be used on the drug boxes. During the project, the randomization list will be kept with the statistician, and other participants in the project will not be aware of the assigned groups.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences

Street address
Taleghani Hospital

City
Ahvaz

Province
Khouzestan

Postal code
6135733184

Approval date
2018-11-30, 1397/09/09

Ethics committee reference number
IR.AJUMS.REC.1397.660

Health conditions studied

1

Description of health condition studied
2nd degree burn wound

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
comparison of healing of the wound

Timepoint
First day then 3 and 7 day later

Method of measurement
Bets Jensen wound assessment tool

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Herbal cream 1 time a day for maximum 2 weeks
Category
Treatment - Drugs

2

Description
Control group: silver sulfadiazine cream 1 time a day for max 2 week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Taleghani Hospital
Full name of responsible person
Amir Siyahpoosh
Street address
Mostan St Amananiye
City
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-6135715794
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+98 61 3333 9995
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amirsiahpoosh@yahoo.com
Web page address
http://htaleghani.ajums.ac.ir/HomePage.aspx?TabID=8577&Site=htaleghani.ajums.ac&Lang=fa-IR

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mohammad Badvi
Street address
Esfand Street, Golestan Road, Ahvaz
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Postal code
6135733184
Phone
+98 61 3336 2414
Email
amirsiahpoosh@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Amir Siahpoosh
Position
Associate Professor
Latest degree
Ph.D.
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

Only a part of the data will be shared

When the data will become available and for how long

The access period will be 6 months after the publication of the results

To whom data/document is available

The obtained data from current study will be available only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail

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

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments