Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effectiveness of wet cupping on moderate and severe acne in patients under treatment with Azithromycin

Protocol summary

Study aim
Determine the effect of wet cupping on moderate and severe acne

Design
A randomized, blinded, controlled clinical trial with a parallel group design of 108 patients, enrolled from 6 August 2018 , and followed for 3 months. Randomization is done via "Blocked Randomization List".

Settings and conduct
The study is performed in the dermatology clinic of Shahid Faghihi Hospital. In this study, patients with mild to moderate acne between the ages of 18-35 years are randomly divided into intervention and control groups through the "Blocked Randomization List". All participants receive classical medicine, but in the intervention group, in addition to classical treatment, cupping is performed. The dermatologist and the person analyzing the information are unaware of the cupping.

Participants/Inclusion and exclusion criteria
Criteria for entering the plan: Includes severe and moderate acne on the face, and informed consent to participate in the study and non- pregnancy and no specific disease including hormonal imbalance, chronic diseases, anemia, other coagulation problems and other infectious diseases. Exit criteria: Includes pregnancy and the emergence of specific illness during treatment, as well as cupping in the past three months and taking roaccutane over the past year.

Intervention groups
In this survey, the studied population is between the ages of 18-35 with moderate or severe acne. Participants are randomly divided into two groups. All participants (intervention group and control group) receive oral antibiotics based on the standard treatment protocol. In the intervention group, wet cupping is done twice, with 6 weeks interval (once at the beginning and second time 6 weeks later).

Main outcome variables
Severity of Acne

General information

Reason for update
At the discretion of the research group, instead of randomization through coins, the Internet randomization "Blocked Randomization List" was used, and unfortunately, the registration of this change in "IRCT" has been forgotten.

Acronym

IRCT registration information
IRCT registration number: **IRCT20180623040199N1**
Registration date: **2018-08-05, 1397/05/14**
Registration timing: **prospective**

Last update: **2020-07-21, 1399/04/31**
Update count: **2**

Registration date
2018-08-05, 1397/05/14

Registrant information

Name
Fatemeh Tabatabaeishourijeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-06, 1397/05/15

Expected recruitment end date
2019-01-05, 1397/10/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of wet cupping on moderate and severe acne in patients under treatment with Azithromycin

Public title

Effectiveness of wet cupping on moderate and severe acne in patients under treatment with Azithromycin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Moderate and severe acne on the face; Informed consent to participate in the study; No pregnancy; Without any specific disease including chronic diseases, hormonal imbalance, anemia, and other coagulation problems, and Aids and other infectious diseases.

Exclusion criteria:

Pregnancy; Occurrence of specific diseases during treatment; Wet cupping in the past three months; Taking roaccutane in the past year.

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, according to the inclusion criteria, patients are selected and then according to the random sequence obtained through the "Blocked Randomization List" (random blocking with 6 blocks), in the same random order, patients will be divided into intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

A dermatologist who checks patients at intervals is unaware of the wet cupping. The analyzer is unaware of the patients whom wet cupping is done for them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics Committee for Biomedical Research

Street address

Thirteenth floor, block A, Central Headquarters of the Ministry of Health and Medical Education, simaye Iran Street between South Felamak and Zarafshan, Ghods Town (West), Tehran.

City

Tehran

Province

Tehran

Postal code

1936773493

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.KMU.REC.1397.096

Health conditions studied

1

Description of health condition studied

Acne

ICD-10 code

L70.0

ICD-10 code description

Xii Diseases of skin and subcutaneous tissues

Primary outcomes

1

Description

Acne

Timepoint

Initially, the sixth week and the twelfth week

Method of measurement

By using Modified Global Acne Grading Score

Secondary outcomes

1

Description

Quality of Life

Timepoint

Initially and the twelfth week

Method of measurement

Questionnaire

2

Description

The prevalent temperament of people with acne

Timepoint

Initially and the twelfth week

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: In the back area between the first to third thoracic vertebra, during the first visit and the sixth week, the cupping will be done. In addition, antibiotic antibiotic azithromycin will be given 3 times a week.

Category

Treatment - Other

2

Description

Control group:They will receive antibiotic azithromycin three times a week, as well as sham cupping.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of the Martyr Faghih Hospital

Full name of responsible person

Mohammam Mahdi Parvizi

Street address

Faghih Hospital, Zand St, Shiraz.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Haleh Tajadini

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Dr-Haleh@yahoo.com

Grant name

124701

Grant code / Reference number

1603003000

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

Fatemeh Tabatabaeishourijeh

Position

Traditional Medicine student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
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Medical doctor

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Traditional Medicine

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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
It is published through the supplementary file

When the data will become available and for how long
6 months

To whom data/document is available
Researchers and other people can access data if they need it

Under which criteria data/document could be used
For using in systematic review articles, reprogramming and modeling can be used in other studies. In case of need, should be emailed to the programmer or entered university site.

From where data/document is obtainable
Executor of plan or University

What processes are involved for a request to access data/document
Email the scheduler,she answers.

Comments
All information is available to others for the advancement of science.