

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of gel of tea tree oil nanoemulsion against clindamycin gel in treatment of acne

Protocol summary

Study aim

Clinical trial of tea tree oil nanoemulsion gel against clindamycin gel in treatment of acne

Design

randomization: equalized blocks, 174 samples will be needed. the phase 3 of the clinical trial will be used

Settings and conduct

First, the aims of the study will explained. On the first day and after 6 weeks, the patients will be visited and the total number of papules, pustules and comedones will be counted. After 3 weeks they will be called and any possible side effects will be asked. The patients will be given a handout to write down the adverse effects including the date of observing the adverse effect.

Sampling will be done in Emam Reza Clinic or the office

Participants/Inclusion and exclusion criteria

Patients with mild to medium acne inclusion criteria: age 15-30 years, filling the consent form, no use of drugs for the last 14 days exclusion criteria: pregnancy, lactation, hormone diseases, physical disabilities Leaving the study: adverse side effects, tendency of the patients

Intervention groups

1. group receiving the nanoemulsion gel 2. group receiving the clindamycin gel

Main outcome variables

Acne severity index, Skin inflammation, total number of acne

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150902023864N4**

Registration date: **2021-10-27, 1400/08/05**

Registration timing: **prospective**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Amir Amani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 218899111824

Email address

aamani@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of gel of tea tree oil nanoemulsion against clindamycin gel in treatment of acne

Public title

Gel of tea tree oil nanoemulsion in treatment of acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No use of any medicine (including body building agents)

in the last 14 days Age: 15-30 years

Exclusion criteria:

Pregnancy Lactation Hormone diseases Acute physical disability

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **174**

Randomization (investigator's opinion)

Randomized

Randomization description

To conceal the data, all the packs will be the same. each pack will contain a label so that the dispenser and the prescriber will not be aware of the contents. The sampling will be performed using Permuted Block Randomization. Group A: To do so, using the online software "Random number generator", block of treatment groups A and B will be generated. Group A: Tea tree oil nanoemulsion gel, Group B: Clindamycin gel Here is example of the first few blocks: AABB ABBA ABAB etc.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Same packaging will be used. A code will be written on the packs. secretary will give the packs to the patients using a randomized list. The practitioner and the statistician will not be aware of the pack contents.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of north khorasan university of medical sciences

Street address

NO. 91, shahriar street

City

Bojnurd

Province

North Khorasan

Postal code

9417694765

Approval date

2021-10-19, 1400/07/27

Ethics committee reference number

IR.NKUMS.REC.1400.114

Health conditions studied

1

Description of health condition studied

acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Inflammatory and noninflammatory lesions

Timepoint

First day- 6th week

Method of measurement

counting lesions using manual lens

Secondary outcomes

1

Description

side effects

Timepoint

first day and 6th week

Method of measurement

questionnaire (any possible side effects)

Intervention groups

1

Description

Intervention group: gel of tea tree oil nanoemulsion: twice daily- after washing the affected area with soap and drying the skin, the medicine will be applied topically. Then, the area should not be washed for two hours. The treatment will continue for two weeks, then the patient will be visited again.

Category

Treatment - Drugs

2

Description

Control group: Clindamycin gel (commercial formulation available in the market)- twice daily- after washing the affected area with soap and drying the skin, the medicine will be applied topically. Then, the area should

not be washed for two hours. The treatment will continue for two weeks, then the patient will be visited again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Clinic

Full name of responsible person

Ali Nazari

Street address

Safa street, Emam Reza Hospital

City

Bojnurd

Province

North Khorasan

Postal code

9417694735

Phone

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Email

amani76@gmail.com

2

Recruitment center

Name of recruitment center

Personal office

Full name of responsible person

Hamid Sooregi

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Madar building, Shariati street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Ahmad Hashemi

Street address

Dolat Boulevard

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North Khorasan

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9414974877

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amani76@gmail.com

Grant name

Grant code / Reference number

4000067

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

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Amir Amani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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shahriar strett

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Amir Amani

Position

acadmic member

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Email

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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

Not applicable

Title and more details about the data/document

All data potentially may be shared

When the data will become available and for how long

Nearly in 3 years

To whom data/document is available

All people

Under which criteria data/document could be used

there is no condition

From where data/document is obtainable

they can email the PI

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

We do our best to deliver the data in a month

Comments