Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the efficacy of combination of doxycycline and topical N-acetyl cysteine versus doxycycline and topical benzoyl peroxide in the treatment of patients with moderate acne vulgaris

Protocol summary

Study aim

Determining the therapeutic effect of the combination of doxycycline and topical N-acetylcysteine with doxycycline and topical benzoyl peroxide in patients with moderate acne

Design

Phase 3, randomized, double blinded, clinical trial with a parallel group design of 40 patients. Due to the lack of similar previous study, we designed a pilot study with 40 patients (20 case and 20 control).

Settings and conduct

this trial will be done in Shahid Faghihi hospital Dermatology ward in Shiraz. neither the patients nor the resident will not know the type of medication. The colleague will put the medications in alike boxes. Codes of randomization will be put on the boxes. The drugs will be given to the patients by the colleague monthly. The codes will not be clarified till the end of research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate acne Married women agree with using contraceptive during the treatment. Exclusion criteria: History of hypersensitivity to the medications used in the study Age below 15 years or above 35 years Unwillingness to participate in the study Inability to come regularly for follow-up visits Use of herbal medicine Receiving systemic anti acne therapies 1 month before the study Receiving topical anti acne therapies 2 weeks before the study Pregnancy and breastfeeding Hepatic diseases Renal diseases Use of nitroglycerin Use of systemic medications that have interaction with the drugs used in the study

Intervention groups

there is two intervention groups group A receive doxycycline 100 mg once a day and N-acetyl cysteine 5% gel group B receive doxycycline 100 mg once a day and Benzoyl peroxide gel 5%

Main outcome variables

Recovery rate of acne from the patient's point of view; Recovery rate based on IGA criteria; Recovery rate based on GAGS criteria; Recovery rate based on CADI criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230921059485N1**
Registration date: **2024-06-27, 1403/04/07**
Registration timing: **prospective**

Last update: **2024-06-27, 1403/04/07**
Update count: **0**

Registration date

2024-06-27, 1403/04/07

Registrant information

Name

Negin Fazelzadeh Haghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3624 6053

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-30, 1403/04/10

Expected recruitment end date

2024-10-01, 1403/07/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the efficacy of combination of doxycycline and topical N-acetyl cysteine versus doxycycline and topical benzoyl peroxide in the treatment of patients with moderate acne vulgaris

Public title
Evaluating the effect of topical N-acetyl cysteine in treatment of acne
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with moderate Acne married females who agree with taking oral contraceptive pills (OCP) during treatment
Exclusion criteria:
below 15 or over 35 years old unwillingness to participate in the study inability to come regularly for follow-up visits use of herbal medicine receiving systemic anti acne therapies 1 month before the study receiving topical anti acne therapies 2 weeks before the study pregnancy and breast feeding hepatic diseases renal diseases use of nitroglycerine use of medications that have interaction with the drugs used in the study history of hypersensitivity to the medications used in the study
Age
From **15 years** old to **35 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided to groups A and B using block randomization and sealed envelope online randomization software. Our colleague will put benzoyl peroxide and N-acetyl cysteine in alike boxes and the code of randomization will be put on the boxes. The codes will not be clarified until the end of research. (allocation concealment)
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blinded. Neither The investigator nor the patients will not know the type of topical medication (benzoyl peroxide or N-acetyl cysteine). The colleague will put the drugs in alike boxes and the code of block randomization will be put on the boxes. The drugs will be given to the patients by the colleague monthly. The codes will not be clarified till the end of research and neither the investigator nor the patients will not know the type of medication till the end of research.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical Research Ethics Committee of Shiraz Medical School
Street address
Zand Avenue, Shiraz Medical School, Building number 3, Third floor, Vice Chancellor for Research Office of Shiraz Medical School, Ethics Committee
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2023-11-27, 1402/09/06
Ethics committee reference number
IR.SUMS.MED.REC.1402.389

Health conditions studied

1

Description of health condition studied
Acne
ICD-10 code
L70.0
ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
Acne severity
Timepoint
1 and 3 month later
Method of measurement
according to Investigator Global Assessment (IGA) score

2

Description
acne severity
Timepoint
1 and 3 months later
Method of measurement
according to Global Acne Grading System (GAGS) score

Secondary outcomes

1

Description
quality of life improvement
Timepoint
1 and 3 months later
Method of measurement
Cardiff Acne Disability Index (CADI) quality of life questionnaire

2

Description
treatment response
Timepoint
after 3 months
Method of measurement
question the patients

Intervention groups

1

Description
Intervention group (group A): combination of doxycycline Hakim company 100 mg once daily and N-acetyl cysteine 5% gel once daily for 3 months. For preparing N-acetyl cysteine 5% gel we will use N-acetyl cysteine powder in the base of sodium carboxy methyl cellulose polymer and some excipients including solvents, moisturizers and antimicrobials will be added too. All the excipients used are allowed.
Category
Treatment - Drugs

2

Description
Control group (B): combination of doxycycline Hakim company 100 mg once daily and benzoyl peroxide 5% gel, Pars Behroozan Jam company for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Fghihi hospital
Full name of responsible person
Negin Fazelzadeh Haghighi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mohammad Hashem Hashempur
Street address
Shiraz University of Medical Sciences, Research vice, Zand street
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7134814336
Phone
+98 71 3235 7252
Email
hashempur@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person

Negin Fazelzadeh Haghighi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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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
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
Title and more details about the data/document
Parts of data will be shared. The patient's data will be kept confidential.
When the data will become available and for how long
Starting 3 months after publication
To whom data/document is available
Data will be available for people working in academic institutions or people working in businesses.
Under which criteria data/document could be used
To commercialize the product and use it widely as an acne treatment.
From where data/document is obtainable
please mail: neginfzd@yahoo.com
What processes are involved for a request to access data/document
please mail: neginfzd@yahoo.com
Comments