Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

efficacy of oral probiotic with doxycyclin in comparison with doxycyclin in acne vulgaris

Protocol summary

Study aim
efficacy of oral probiotic with doxycyclin in comparison with doxycyclin in acne vulgaris

Design
This study is designed as randomized double blinded in the year of 2019-2020. 100 patients from Rasool Akram hospital with age between 18 to 35 with Moderate acne (grade 2 or 3 of global acne assessment scale with totally 20 to 50 inflammatory lesion) randomly will divide with Excel software into 50 equal control and intervention group.

Settings and conduct
patients will chosen from 100 sealed envelops for any patient with equal code A or B from a box. just the principle investigator knows about patient and no one else dont know about any code or treatment plan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient with Moderate acne (grade 2 or 3 of global acne assessment scale with totally 20 to 50 inflammatory lesion) people with age between 18 to 35 exclusion criteria : Pregnant or Breast feeding female patient Receiving antibiotics in last months Patient with dyspepsia

Intervention groups
all of patients will treat with antibacterial shampoo and Adapalen cream as uniform topical treatment. control group receive doxycycline capsule daily. the intervention group receive doxycycline capsule plus probiotic capsule daily. All of patients acne lesions will photographed with digital camera before treatment and one , two and three months after treatments. treatment response will assess with global acne grading and acne severity index

Main outcome variables
treatment response will assess with global acne grading and acne severity index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190830044645N1**
Registration date: **2019-10-01, 1398/07/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-01, 1398/07/09**
Update count: **0**

Registration date
2019-10-01, 1398/07/09

Registrant information

Name
Masoumeh Mohamadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4445 3955

Email address
mohamadi11248@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
efficacy of oral probiotic with doxycyclin in comparison with doxycyclin in acne vulgaris

Public title
Efficacy of oral Probiotic with Doxycyclin in comparison with Doxycyclin in Acne Vulgaris
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with Moderate acne (grade 2 or 3 of global acne assessment scale with totally 20 to 50 inflammatory lesion) people with age between 18 to 35
Exclusion criteria:
Pregnant or Breast feeding female patient Receiving antibiotics in last months Patient with dyspepsia
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients enter the treatment groups on a 1: 1 ratio using Excel software. From a box with 100 sealed envelopes, each patient is selected with one envelope containing either A or B. (Method I: A and Method II: B)
Blinding (investigator's opinion)
Double blinded
Blinding description
just the principle investigator knows about patient and no one else dont know about any code or treatment plan. Patients in the intervention and control groups did not know which treatment group they entered. These patients are not aware of the type of treatment group that they enter. Both groups receive standard and identical treatment. The intervention group uses probiotic capsule in addition to standard treatment. The control group received only standard treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences Ethics Committee
Street address
Satarkhan street , Niyayesh Avenue , Rasool Akram hospital , Dermatology Department Office
City
Tehran
Province
Tehran
Postal code
1469935947
Approval date
2019-03-09, 1397/12/18
Ethics committee reference number
IR.IUMS.FMD.REC.1398.130

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
acne grading in global acne grading and acne severity index
Timepoint
before intervention, one , two and three months after treatment
Method of measurement
global acne grading and acne severity index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients will treat with antibacterial shampoo and Adapalen cream as uniform topical treatment. The intervention group receive doxycycline capsule plus probiotic capsule daily. All of patients acne lesions will photographed with digital camera before treatment and one , two and three months after treatments. treatment response will assess with global acne grading and acne severity index
Category
Treatment - Drugs

2

Description

Control group:patients will treat with antibacterial shampoo and Adapalen cream as uniform topical treatment. control group receive only doxycycline capsule dailyand do not receive d probiotic capsule. All of patients acne lesions will photographed with digital camera before treatment and one , two and three months after treatments. treatment response will assess with global acne grading and acne severity index

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Masoumeh Mohamadi

Street address

Satarkhan street , Niyayesh Avenue , Rasool Akram hospital , Dermatology Department Office

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Doctor Seyed Abbas Motavallian

Street address

Iran University of Medical Sciences , near Milad Tower, Hemmat highway

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Postal code

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+98 21 8670 2503

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research@iums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Masoumeh Mohamadi

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

Medical doctor

Other areas of specialty/work

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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
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
all collected deidentified IPD to be shared
When the data will become available and for how long
starting after publication
To whom data/document is available
our data is available for researchers.
Under which criteria data/document could be used
data for analysis and usage in research programs can be use , but he should confirm the data is belong to us.
From where data/document is obtainable
contact email : mohamadi11248@gmail.com
What processes are involved for a request to access data/document
after one week he receive data
Comments