Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect probiotic on resistant chronic urticaria

Protocol summary

Study aim
Effects of probiotic on resistant chronic urticaria severity - quality of life
Design
All of participants divided into two groups based on simple randomization. Each group has 20. This is phase 3
Settings and conduct
This is a double blind study in tooba clinic and boali hospital in sari
Participants/Inclusion and exclusion criteria
Inclusion criteria; resistant chronic urticaria, 5 to 30 years old Exclusion criteria: use probiotic, second arry urticaria, other disorders
Intervention groups
20 patients with chronic urticaria take antihistamines and probiotic
Main outcome variables
Resolution chronic urticaria severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110531006660N9**
Registration date: **2020-07-24, 1399/05/03**
Registration timing: **retrospective**

Last update: **2020-07-24, 1399/05/03**
Update count: **0**
Registration date
2020-07-24, 1399/05/03

Registrant information
Name
Javad Ghafari
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-22, 1399/05/01
Expected recruitment end date
2020-08-22, 1399/06/01
Actual recruitment start date
2019-06-22, 1398/04/01
Actual recruitment end date
2019-06-22, 1398/04/01
Trial completion date
2020-02-20, 1398/12/01

Scientific title
Effect probiotic on resistant chronic urticaria

Public title
Probitic in chronic urticaria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Resistant chronic urticaria 5 to 30 years old
Exclusion criteria:
Consumption of probiotic in the last 2 months Second urticaria other Known disorders consumption of antibiotic in the last 2 months
Age
From **5 years** old to **30 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, each patient selected based on table of random divided to each group . such as 1,4,7 and ...in one group; 2,3,5,6,8,9 and ...in another group based on randomization number.
Blinding (investigator's opinion)
Double blinded
Blinding description
All of participants, physician, data collector, data analyzer. after selection of patients, take drug or placebo from pharmacy. only pharmacologist known about treatment. finally data send to supervisor without name and without kind of treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical sciences
Street address
Pasadaran Blvd-Boali hospital
City
Sari
Province
Mazandaran
Postal code
4815838477
Approval date
2018-08-20, 1397/05/29
Ethics committee reference number
IR.MAZUMS.REC.1398.163

Health conditions studied

1

Description of health condition studied
Chronic urticaria
ICD-10 code
L50.1
ICD-10 code description
Idiopathic urticaria

Primary outcomes

1

Description
Resolution chronic urticaria severity
Timepoint
Before, 4 and 8 weeks after treatment
Method of measurement
Questionnaire- UAS7 and QOLI

Secondary outcomes

1

Description
Resolution chronic urticaria quality of life
Timepoint
Before, 4 and 8 weeks after treatment
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: 20 patient with CU resistant to treatment treated with cetirizine 10mg BID/day and probiotic 1000 mg /day for 8 weeks. all of them completing questionnaire before, 4 and 8 weeks after treatment.
Category
Treatment - Drugs

2

Description
Control group: 20 patient with CU resistant to treatment treated with cetirizine 10mg BID/day and placebo one cap sol /day for 8 weeks. all of them completing questionnaire of severity and quality of life before, 4 and 8 weeks after treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tooba clinic and boali hospital
Full name of responsible person
Javad Ghaffari
Street address
Pasdaran blvd

City
Sari
Province
Mazandaran
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4815838477
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Reza Alizadeh Navaei
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Reza.nava@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Javad Ghaffari
Position
Professor
Latest degree
Subspecialist
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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

Yes

When the data will become available and for how long

After end of research

To whom data/document is available

All

Under which criteria data/document could be used

No

From where data/document is obtainable

Email

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

Email

Comments