Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of therapeutic effects of Curcumin & Crucina on thyroid eye disease (TED)

Protocol summary

Study aim
Assessment of therapeutic effects of curcumin and croucin on thyroid eye disease
Design
Randomized double blind clinical trial study (including intervention and control groups).
Settings and conduct
The patients referred to oculoplasty clinic of Khatam al anbia hospital by endocrinologists. After initial evaluation if they meet the inclusion criteria and singing the consent form, will be assigned to the study. Patient assessment sheet will be completed. Allocation to each group will be done by lottery randomization. Before drug prescription, they referred to hospital lab to provide blood sample (which after separation of plasma and cell, preserved in -80 freezer). Then the main drug (if needed) plus one of proposed intervention complementary drugs (curcumin, croucin or placebo) has supplied for the patient. Clinical evaluation at first and second months after that will be done. Another blood sample will be taken at the 2nd month and have preserved same as the first. Necessary treatment for the patients will be continued.
Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with Grave's disease and eye involvement and clinical activity score (CAS) more than 1
Intervention groups
Group 1: Steroid plus curcumin 1 capsule/day for 2 months (Sina Curcumin 80 mg capsule, Exir Nano Sina, Mashhad, Iran) Group 2: Steroid plus crocin (two 15 mg tablet daily for 2 months , Krocina, Samisaz Co. Mashhad, Iran) Group 3: curcumin, 1 capsule/day for 2 months without steroid Group 4: crosin (two 15 mg tablet daily for 2 months) without steroid Group 5: Placebo (polysorbate 80, Exir Nano Sina, Mashhad, Iran) with steroid for 2 months Group 6: Placebo without steroid for 2 months
Main outcome variables
Clinical activity score; serologic levels of IL2 & TNFa

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171207037777N1**
Registration date: **2019-04-09, 1398/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-09, 1398/01/20**
Update count: **0**
Registration date
2019-04-09, 1398/01/20

Registrant information
Name
Aliakbar Sabermoghaddam Ranjbar
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-22, 1397/09/01
Expected recruitment end date
2019-09-22, 1398/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Assessment of therapeutic effects of Curcumin & Crucina on thyroid eye disease (TED)

Public title
Alternative medicine in thyroid eye disease (TED)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Thyroid eye disease with clinical activity score (CAS) equal to 1 or more
Exclusion criteria:
No consent Poor coopration
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
First of all the patients allocated in 2 groups, according to indication for steroid use or not (depending to clinical activity score as described in proposal). Then by simple randomization (by drawing a ballot through a bottle containing lots labeled A, B or C), the patients allocated in groups A, B or C by lottery.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs packed in similar bottles labeled A, B or C. The patient will receive one pack of drug. The usage information is in the bottle so that the clinician hasn't any information about the contents of the packages. In the lab, the blood samples were reserved under the name of patients but the reporter of the results will be unaware from the drugs used by the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad university of medical sciences
Street address
N0. 51, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2018-06-27, 1397/04/06
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.006

Health conditions studied

1

Description of health condition studied
Thyroid eye disease
ICD-10 code
E05.0
ICD-10 code description
Thyrotoxicosis with diffuse goiter

Primary outcomes

1

Description
Clinical activity of eye involvement
Timepoint
Before, 1 & 2 months after initiation of intervention
Method of measurement
Clinical evaluation

2

Description
Serologic level of IL2
Timepoint
Before and 2 months after initiation of intervention
Method of measurement
ELISA

3

Description
Serologic level of TNFa
Timepoint
Before and 2 months after initiation of intervention
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Steroid plus curcumin 1 capsule/day for 2 months (Sina Curcumin 80 mg capsule, Exir Nano Sina, Mashhad, Iran)
Category
Treatment - Drugs

2

Description
Intervention group 2: Steroid plus crocin (two 15 mg tablet daily for 2 months , Krocina, Samisaz Co. Mashhad, Iran)
Category
Treatment - Drugs

3

Description
Intervention group 3: curcumin, 1 capsule/day for 2 months (Sina Curcumin 80 mg capsule, Exir Nano Sina, Mashhad, Iran)without steroid
Category
Treatment - Drugs

4

Description
Intervention group 4: crosin (two 15 mg tablet daily for 2 months , Krocina, Samisaz Co. Mashhad, Iran) without steroid
Category
Treatment - Drugs

5

Description
Control group 1: placebo (polysorbate 80, Exir Nano Sina, Mashhad, Iran) with steroid for 2 months
Category
Placebo

6

Description
Control group 2: placebo (polysorbate 80, Exir Nano Sina, Mashhad, Iran) without steroid for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam al anbia eye hospital
Full name of responsible person
Akbar Derakhshan
Street address
No. 7, Gharani 41, Gharani Boulevard.
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Province
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9195965919
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Email
KH.PR@mums.ac.ir
Web page address
http://khatam.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghoddi
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Aliakbar Sabermoghaddam Ranjbar

Position
Associate prof.
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
No. 16, Edalat 21 Ave., Ahmadabad st.
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Demographic data, clinical and serologic results
When the data will become available and for how long
After Sep. 2020
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Any publications should include researchers of this study and also refer to published articles
From where data/document is obtainable
Aliakbar Sabermoghaddam Ranjbar, Khatam al anbia eye hospital
What processes are involved for a request to access data/document
E mail to corresponding researcher including necessary data and how to use
Comments