

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

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

Protocol summary

Study aim

Assessment of therapeutic effects of curcumin and crocin 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 signing 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, crocin 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: crocin (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 & TNFα

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

Country

Iran (Islamic Republic of)

Phone

+98 51 3845 6406

Email address

saberaa@mums.ac.ir

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 cooperation

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.

City

Mashhad

Province

Razavi Khorasan

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9195965919

Phone

+98 51 3728 1401

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

Street address

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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

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No. 16, Edalat 21 Ave., Ahmadabad st.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Aliakbar Sabermoghaddam Ranjbar

Position

Associate professor

Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

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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