

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the therapeutic effects of Trehalose in aortic inflammation in patients with cancer

Protocol summary

Study aim

Reduction of aortic inflammation in patients with cancer by Trehalose therapeutic effect

Design

This study has been designed as a case study

Settings and conduct

Razavi hospital

Participants/Inclusion and exclusion criteria

Entry conditions for trial: Patients with TBR higher than 1.6 Exit criteria for trial : Diabetic patients with HbA1C higher than 6.5 Patients who receive anti inflammatory medicine such as statins and aspirin Patients who diagnosed with vasculitis or bacterial infection

Intervention groups

Trehalose 15 gr/ml

Main outcome variables

The investigation of improvement in aortic vascular inflammation by using Pet scan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130829014521N20**

Registration date: **2022-06-07, 1401/03/17**

Registration timing: **prospective**

Last update: **2022-06-07, 1401/03/17**

Update count: **0**

Registration date

2022-06-07, 1401/03/17

Registrant information

Name

Amirhossein Sahebkar

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1882 9260

Email address

sahebkar@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the therapeutic effects of Trehalose in aortic inflammation in patients with cancer

Public title

Trehalose and aortic inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cancer patients with aortic inflammation with a cutoff of 1.6 or more for the TBR in the first scan

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 2

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Two cancer patients with aortic inflammation and TBR above 1.6 in the first scan will be enrolled in this study. Patients will receive a single dose of intravenous injection of trehalose (15 g / 100 ml) and will be re-scanned a week later to assess the therapeutic effects of trehalose on aortic inflammation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences (Ethics Committee)

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.MUMS.REC.1401.026

Health conditions studied

1

Description of health condition studied

Aortic inflammation in patients with cancer

ICD-10 code

I77.6

ICD-10 code description

Arteritis, unspecified

Primary outcomes

1

Description

Investigation of aortic inflammation with (18F-FDG PET) scan

Timepoint

one week after administration of trehalose

Method of measurement

(18F-FDG PET) scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one dose of Trehalose by intravenous injection (15 gr/ml)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razavi hospital of Mashhad

Full name of responsible person

Farshad Emami

Street address

Kalantari highway, Mashhad, Khorasan razavi, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

30007273010022

Phone

+98 51 3666 8888

Email

farshademami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Vice-Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad,

City

Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresraech@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
Amirhossein Sahebkar
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmaceutical biotechnology
Street address
School of Pharmacy, East door of Ferdowsi University,
Azadi Square, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 1882 9260
Fax
+98 51 1882 3251
Email
sahebkar@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences
Full name of responsible person
Dr.Amirhossein Sahebkar
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmaceutical biotechnology
Street address
School of Pharmacy, East door of Ferdowsi University,
Azadi Square, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 1882 9260
Fax
+98 51 1882 3251
Email
sahebkar@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Shabnam radbakhsh
Position
P.h.D Student
Latest degree
Ph.D.
Other areas of specialty/work
Medical biotechnology
Street address
Bahonar blv
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948974
Phone
+98 51 3882 3258
Email
Radbakhshs971@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It will be available If there be any requirements

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code

No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available