

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the effect of Wet cupping on known cardiovascular risk factors and anti-heat shock protein-27 in patients with metabolic syndrome

Protocol summary

Study aim

Investigating the effect of Wet cupping on Coronary risk factors and anti-heat shock protein in patients with metabolic syndrome

Design

A clinical trial, with the control and intervention groups, single-blinded, was randomized on 136 patients with metabolic syndrome.

Settings and conduct

In wet-cupping, a physician or a trained person create a swelling with a glass and a suction device, in the area between the two scapulae in the opposite side of the thymus gland, then 7 to 14 superficial scratches were created on the skin parallel to the midline of the body with a distance of 3 to 5 mm between scratches. The length of each scratch was between 5 to 10 mm, then 3 to 5 consecutive stages, each stage lasting 3 to 5 minutes, are done. Finally, 50 to 70 cc of the participant's blood was taken. Then, the cupping area was completely covered with gas and glue.

Participants/Inclusion and exclusion criteria

Males and females aged between 18 and 65 with metabolic syndrome were allowed to participate in the study; also, participants had not any infectious diseases or coagulopathies, and did not consume any therapeutic diet and/or medication. Individuals with a history of stroke and ischemic heart disease, or consume a therapeutic diet and medication were not allowed to participate in the study.

Intervention groups

The control group was recommended to follow a special diet for a month. Next, the second blood sample was taken from them. Then they followed the diet for another month. Finally, the third blood sample was taken from them. The intervention group was prescribed with the diet and wet-cupping by a specialist. After a month a blood sample (20 cc) was taken from them and the diet

and second wet-cupping were prescribed to them again. After another month the last blood sample was taken from them.

Main outcome variables

prevention of hypertension; reduction in anti-hsp27 level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201101049213N1**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **retrospective**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Ali Ebrahimi Dabagh

Name of organization / entity

Varastegan Institute for Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-31, 1396/05/09

Expected recruitment end date

2017-12-17, 1396/09/26
Actual recruitment start date
 2017-07-31, 1396/05/09
Actual recruitment end date
 2017-12-17, 1396/09/26
Trial completion date
 2018-02-16, 1396/11/27

Scientific title
 Investigating the effect of Wet cupping on known cardiovascular risk factors and anti-heat shock protein-27 in patients with metabolic syndrome

Public title
 The effect of Wet cupping on metabolic syndrome

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having metabolic syndrome Age range: 18 to 65 years old Male or female Resident in Mashhad city Absence of consumption of any therapeutic diet and/or medication (antilipidemic medications) Absence of infectious diseases or coagulopathies
Exclusion criteria:
 Ages under 18 and above 65 years old Individuals with the history of stroke and ischemic heart disease Consuming a specific therapeutic diet and/or medication Diabetes mellitus type 1 Presence of any infectious disease based on the patient statement, but not be documented by laboratory tests

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **136**
 Actual sample size reached: **136**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this randomized clinical trial study, after excluding criteria 136 patients will be recruited. Individuals will be randomized by PASS application and dual block randomization method. One hundred and thirty-six number will be divided into two groups (A: Intervention group, B: Control group), the codes and names are written on a paper and are put in a paper packet. The first participant picks up packet number 1 and is guided to the respective group. Then the second participant picks up packet number 2 and the process continues until all participants are allocated. Due to the type of treatment, there is no possibility of allocation concealment, and blindness could be only single-blind.

Blinding (investigator's opinion)
 Single blinded

Blinding description

All participants were not informed about the existence in the control or intervention groups.

Placebo
 Not used

Assignment
 Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Human Research Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2016-12-24, 1395/10/04

Ethics committee reference number

IRMUMSREC.1395.468

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

Fasting Blood Glucose (FBG)

Timepoint

Measurement of the FBG at the beginning of the study and a month, 2 months after finishing Wash Out Diet

Method of measurement

Blood sample

2

Description

HDL

Timepoint

Measurement of the HDL at the beginning of the study

and a month, 2 months after finishing Wash Out Diet

Method of measurement

Blood sample

3

Description

LDL

Timepoint

Measurement of the LDL at the beginning of the study and a month, 2 months after finishing Wash Out Diet

Method of measurement

Blood sample

4

Description

Cholesterol

Timepoint

Measurement of the blood cholesterol at the beginning of the study and a month, 2 months after finishing Wash Out Diet

Method of measurement

Blood sample

5

Description

triglyceride

Timepoint

Measurement of the blood triglyceride at the beginning of the study and a month, 2 months after finishing Wash Out Diet

Method of measurement

Blood sample

6

Description

Anti-hsp27

Timepoint

Measurement of the anti-hsp27 at the beginning of the study and a month, 2 months after finishing Wash Out Diet

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The diet and wet-cupping treatment were prescribed to the intervention group by a specialist. After a month, blood samples (20 cc) of the participants were taken and the diet and second wet-cupping treatment were prescribed to individuals again. After another month the last blood samples were taken from participants. Wet-cupping was performed by a physician

or a trained person as general type. A swelling with a glass and a suction device was created, in the area between the two scapulae in the opposite side of the thymus gland, and thereafter, some superficial scratches were created on the skin parallel to the midline of the body with a distance of 3 to 5 mm between scratches. The length of each scratch was between 5 to 10 mm. 7 to 14 scratches were created, as they covered the entire cupping area. Finally, cupping was done in 3 to 5 consecutive stages; each stage lasted 3 to 5 minutes. At the end of cupping, 50 to 70 cc of the participant's blood was taken, through dilatation and aspiration of capillaries. Then, the cupping area was completely covered with gas and glue.

Category

Treatment - Devices

2

Description

Control group: The control group was recommended to follow a special diet for one month. Next (after 1 month), the second blood sample was taken from them. Then they followed the diet for another month. Finally, the third blood sample was taken from them.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratory of Imam Reza Hospital

Full name of responsible person

Maryam Mohammadi

Street address

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2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Maryam Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Maryam Mohammadi
Position
A clerk at Mashhad University of Medical Sciences
Latest degree
Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available