

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Association between exposure to Trihalomethanes (THMs) in chlorinated and ozone/chlorinated swimming pools and metabolome-wide

Protocol summary

Study aim

Association between exposure to Trihalomethanes (THMs) in chlorinated and ozone/chlorinated swimming pools and metabolome-wide in swimmers

Design

This study is a randomized, single blinded, parallel design clinical trial, with two intervention groups (Swimmers in chlorinated and Ozone/chlorinated swimming pools).

Settings and conduct

This study is at the filed of environmental risk factors and it will be conducted at swimming pools of Tehran city. After obtaining an informed written consent, volunteers are randomly divided into two groups of 29 (58 totally), in which the level of exposure of individuals with Trihalomethanes (THMs) in two types of swimming pools (1) chlorinated (intervention group) and (2) Ozone/chlorinated (control group) (In parallel) as well as the metabolome wide of individuals before and after swimming will be measured. Participants are asked to swim in the pool for 40 minutes. In this study, in order to assess the exposure of participants in each swimming pool, the THMs in indoor air of swimming pools and the THMs in the alveolar air of participants before and after swimming are measured. Also, the main outcome of this study, metabolome levels and changes, will be investigated through their blood samples. All investigators of study outcomes (blood and alveolar air), will be unaware of the allocations.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Young subjects(18- 40 year) and Healthy. Exclusion criteria: Smokers, Alcoholic, and professional swimmers.

Intervention groups

intervention group1: Participants in the first group will be asked once to swim in chlorinated swimming pool for 40 minutes. intervention group 2: Participants in the second group will be asked once to to swim in ozone/chlorinated swimming pool for 40 minutes.

Main outcome variables

Levels of metabolome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190515043594N1**

Registration date: **2019-10-28, 1398/08/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-28, 1398/08/06**

Update count: **0**

Registration date

2019-10-28, 1398/08/06

Registrant information

Name

Ahmad jonidi jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2021-03-06, 1399/12/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Association between exposure to Trihalomethanes (THMs) in chlorinated and ozone/chlorinated swimming pools and metabolome-wide

Public title

Investigation the health effects of exposure to Trihalomethanes (THMs) in swimming pools

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Young adults (18-40 years) Healthy

Exclusion criteria:

Smoker Alcoholic Professional swimmers

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to random allocation of individuals in two groups, the permuted block randomization by using the web based software (www.sealedenvelope.com) will be applied. It should be noted that the length of blocks will be 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

All investigators of study outcomes (blood and alveolar air), will be unaware of the allocations. Also, when the statistical model of the primary and secondary results is not complete, the randomization code will not be broken.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Besides Milad Tower, Hemmat Highway.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-06-16, 1398/03/26

Ethics committee reference number

IR.IUMS.REC.1398.320

Health conditions studied**1****Description of health condition studied**

The effects of chlorination and ozonation swimming pools (exposure to THMs) on metabolome profile levels

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Metabolome profile levels. The metabolome represents the complete set of molecule/metabolites in a biological cell, tissue, organ or organism, which are the end products of cellular processes.

Timepoint

At this study, the biological samples (blood) of swimmers before and 15 minutes after swimming will be collected.

Method of measurement

High- Nuclear Magnetic Resonance spectroscopy (H-NMR).

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Participants in the first group will be asked once to swim in chlorinated swimming pool for 40 minutes.

Category

Lifestyle

2**Description**

Intervention group 2: Participants in the second group will be asked once to swim in Ozone/ chlorinated

swimming pool for 40 minutes.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hejab Swimming Pool

Full name of responsible person

Ali Heidari

Street address

Hijab Street, Keshavarz Boulevard.

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2

Recruitment center

Name of recruitment center

Koosar Swimming Pool

Full name of responsible person

Mansour Faridi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran University of Medical Sciences

Proportion provided by this source

45

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

2

Sponsor

Name of organization / entity

Iran National Science Foundation

Full name of responsible person

Dr. Iman Eftekhari

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No. 33, 5th Alley, North Karegar Avenue.

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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

Iran National Science Foundation

Proportion provided by this source

55

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

Email

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Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ahmad Jonidi Jafari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Environmental Health

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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