

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating and comparing the expression of cellular senescence genes and inflammatory factors in two groups of elderly and young

#### Protocol summary

##### Study aim

General Objective: To determine the relationship between the expression of cellular senescence genes and inflammatory factors with age in healthy individuals  
Specific Objectives: To determine the activity of the beta-galactosidase enzyme in peripheral blood mononuclear cells (PBMC) in case and control groups To determine the expression of p16, p21 genes in peripheral blood mononuclear cells in case and control groups Determination and comparison of TNF $\alpha$ , IL-6 gene expression in peripheral blood mononuclear cells in case and control groups Determination of the relationship between p16, p21, TNF $\alpha$  and IL-6 gene expression in peripheral blood mononuclear cells and age in healthy subjects Determination of the relationship between beta-galactosidase enzyme activity in peripheral blood mononuclear cells and age in healthy subjects

##### Design

Cross-sectional, observational, comparative, unblinded study on 39 people in each group

##### Settings and conduct

Healthy elderly people who meet the inclusion criteria for the case group and other healthy individuals aged 18-39 who meet the inclusion criteria for the control group and do not meet the exclusion criteria will be included in the study after obtaining informed consent

##### Participants/Inclusion and exclusion criteria

Inclusion criteria for the case group body mass index of 25-32 kg/m<sup>2</sup> Age over 65 years old No acute or chronic infections and inflammations No diabetes or thyroid diseases Inclusion criteria for the control group: body mass index of 18.5-24.9 kg/m<sup>2</sup> -Age 18-39 years - No acute or chronic infections and inflammations

##### Intervention groups

observational study

##### Main outcome variables

p21, p16, TNF $\alpha$ , IL-6 genes and beta-galactosidase activity, in PBMCs. The gene expression will be examined by Polymerase chain reaction (PCR) and the activity of

beta-galactosidase will be examined by staining.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220727055563N3**

Registration date: **2026-05-18, 1405/02/28**

Registration timing: **prospective**

Last update: **2026-05-18, 1405/02/28**

Update count: **0**

##### Registration date

2026-05-18, 1405/02/28

##### Registrant information

##### Name

Hamid Zand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2207 7424

##### Email address

hamidzand@gmail.com

##### Recruitment status

**Not yet recruiting**

##### Funding source

##### Expected recruitment start date

2026-07-21, 1405/04/30

##### Expected recruitment end date

2026-10-23, 1405/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigating and comparing the expression of cellular senescence genes and inflammatory factors in two groups of elderly and young

### Public title

Investigating biological age with cellular senescence genes in blood polynuclear cells

### Purpose

Diagnostic

### Inclusion/Exclusion criteria

#### Inclusion criteria:

people with a body mass index of 18.5-24.9 kg/m<sup>2</sup>

#### Exclusion criteria:

Having other diseases that affect inflammation and cellular aging, including cancer

### Age

From **18 years** old to **85 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **39**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of NNFTRI

##### Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1981619573

#### Approval date

2025-07-23, 1404/05/01

## Ethics committee reference number

IR.SBMU.NNFTRI.REC.1404.038

## Health conditions studied

### 1

#### Description of health condition studied

Investigating and comparing the expression of cellular senescence genes and inflammatory factors in healthy elderly and young

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Expression of senescence related genes in PBMCs

#### Timepoint

once

#### Method of measurement

In Blood

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The study is an observational and comparative study between older and younger people.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran

##### Full name of responsible person

Hamid Zand

##### Street address

No. 7, West Arghavan Ave., Farahzadi Blvd.

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##### Postal code

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##### Email

hamidzand@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Afshin Zarghi

**Street address**

No. 7, West Arghavan Ave., Farahzadi Blvd

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**Province**

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hamid Zand

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

Professor

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**Province**

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**Phone**

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**Fax****Email**

hamidzand@gmail.com

## 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**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Yes - There is a plan to make this available

### **Data Dictionary**

Yes - There is a plan to make this available

### **Title and more details about the data/document**

Data can potentially be shared after individuals are de-

identified.

### **When the data will become available and for how long**

After the study is fully completed and the results are published in reputable scientific journals

### **To whom data/document is available**

Researchers working in academic and scientific institutions

### **Under which criteria data/document could be used**

In cases where this data helps solve a problem in the area of research

### **From where data/document is obtainable**

Main investigator

### **What processes are involved for a request to access data/document**

Clearly state the reason for the request and the results of its use.

### **Comments**