

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 α , IL-6 gene expression in peripheral blood mononuclear cells in case and control groups Determination of the relationship between p16, p21, TNF α 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/m² 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/m² -Age 18-39 years - No acute or chronic infections and inflammations

Intervention groups

observational study

Main outcome variables

p21, p16, TNF α , 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

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/m²

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

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Tehran

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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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 updating data

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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

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