Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 TNFα, IL-6 gene expression in peripheral blood mononuclear cells in case and control groups Determination of the relationship between p16, p21, TNFα 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, TNFα, 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

Recruitment complete

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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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

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Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
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Professor
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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