

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of weighted contact lens on physiological nystagmus in young normal people

Protocol summary

Study aim

The design and construction of a lens is heavier than ordinary lenses and its effect on the parameters of nystagmus evoked by optocentric stimulation in healthy young people and its generalization in the treatment of people with vertigo.

Design

A control clinical trial with parallel groups was performed on 32 patients with and without lenses (conventional and weighted).

Settings and conduct

This study will be done to evaluate the effect of weighted lens designed for nystagmus suppression and reduction of dizziness in the balance system evaluation clinic of Shahid Beheshti School of Rehabilitation Sciences in two stages (test-retest)(two weeks apart)using VNG test .

Participants/Inclusion and exclusion criteria

Age range between 18 and 25 years
Absence of vision problems and ocular motor muscles
Absence of neurological and psychological problems
Do not use drugs that affect the central system during the 48 hours before the test
Do not use caffeine and alcohol for 48 hours before the test
Absence of any spontaneous nystagmus
Reluctance to cooperate for any reason
Inability to perform the test for any reason

Intervention groups

Without lens(control)- with conventional lens - with weighted lens

Main outcome variables

Vertigo- Nystagmus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220119053761N1**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **prospective**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

Registration date

2022-02-02, 1400/11/13

Registrant information

Name

Majid Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1721

Email address

m_ashrafi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of weighted contact lens on physiological nystagmus in young normal people

Public title

The effect of weighted contact lens on physiological nystagmus in young normal people

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range between 18 and 25 years - No vision problems and eye movement muscles - No neurological and psychological problems - No use of drugs affecting the central system during the 48 hours before the test - No use of caffeine and alcohol in the 48 hours before the test - Absence of any spontaneous nystagmus

Exclusion criteria:

Age

From **18 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

N/A

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

Research Ethics Committees of Vice- Chancellor in Research Affairs- Shahid Beheshti University of M

Street address

Shahid Chamran Highway, Yemen St., next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-01-09, 1400/10/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.711

Health conditions studied

1

Description of health condition studied

Vertigo

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Decrease of nystagmus SPV

Timepoint

At the beginning of the study and repeat it two weeks later

Method of measurement

videonystagmography(VNG) test

Secondary outcomes

1

Description

Reduce of vertigo

Timepoint

During the initial evaluation and two weeks later

Method of measurement

VNG test

Intervention groups

1

Description

Intervention group: Using a weighted and conventional lens

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

school of Rehabilitation Sciences Shahid Beheshti

Full name of responsible person

Majid Ashrafi

Street address

Imam Hossein Square - Damavand St. (New Tehran) - in front of Bouali Hospital - Faculty of Rehabilitation Sciences Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1721

Email

m_ashrafi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

افشین زرقي

Street address

Shahid Chamran Highway, Yemen St., next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

zarghi@sbmu.ac.ir

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

Majid Ashrafi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

Street address

Imam Hossein Square - Damavand St. (New Tehran) - in front of Bouali Hospital - Faculty of Rehabilitation Sciences Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1721

Email

m_ashrafi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Majid Ashrafi

Position

استاديار

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

Street address

Imam Hossein Square - Damavand St. (New Tehran) - in front of Bouali Hospital - Faculty of Rehabilitation Sciences Shahid Beheshti University of Medical Sciences-Department of Audiology

City

Tehran

Province

Tehran

Postal code

161691311

Phone

+98 21 7756 1721

Email

m_ashrafi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Majid Ashrafi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Audiology

Street address

Imam Hossein Square - Damavand St. (New Tehran) - in front of Bouali Hospital - Faculty of Rehabilitation Sciences Shahid Beheshti University of Medical Sciences-Department of Audiology

City

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Postal code

1616913111

Phone

+98 21 7756 1721

Email

m_ashrafi@sbmu.ac.ir

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

Potentially shareable after unidentifiable individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is no prohibition on using the data for practical use of the manufactured lens

From where data/document is obtainable

By e-mail to m_ashrafi@sbmu.ac.ir

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

After sending the request to the university email, the data will be sent within two working days

Comments