# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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

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## Sponsors / Funding sources

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**Sponsor**
**Name of organization / entity**
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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**
Majid Ashrafi
**Position**
Assistant Professor
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Audiology
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## Person responsible for scientific inquiries

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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**

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**