

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of the effectiveness of foam and rigid minerva braces in cervical spine movements

Protocol summary

Study aim

Determining the degree of movement immobilization of two braces for proper prescription

Design

Eligible men will be identified by the student through a public announcement in the city of Isfahan (invitation to cooperation poster) and if they wish to participate in the study, they will be invited to Isfahan University of Medical Sciences, Faculty of Rehabilitation, Musculoskeletal Research Center. This project has three phases: 1- implementation of the plan and sampling 2- data analysis 3- thesis writing. This study is double-blind, and both the researcher and the subject are blind

Settings and conduct

Using a 3D motion analysis device and three markers, we check the cervical range of motion before and after wearing two rigid and foam Minerva braces. This study is conducted in the Isfahan Faculty of Rehabilitation of Medical Sciences

Participants/Inclusion and exclusion criteria

1- Men between 18 and 40 years old, due to the changes in the movement of the cervical vertebrae during growth and the increase in the prevalence of joint disorders in the neck area in older ages, can affect the range of motion in this area. 2- Cervical vertebrae should have no history of previous injury Exclusion criteria (based on self-report): 1- The existence of any systematic skin or skeletal damage that makes it impossible to wear a brace 2- Presence of pain, muscle spasms, arthritis, neurological disease, and any history of round surgery

Intervention groups

In this study, a group of men is used in order to know the immobility of the brace before and after the intervention

Main outcome variables

type of brace Extension cervical range of motion Flexion cervical range of motion Axial rotation cervical range of motion Lateral Extension cervical range of motion Age Weight height

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221129056658N1**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

Iran Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3277 0595

Email address

o.stufan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of foam and rigid
minerva braces in cervical spine movements

IR.MUI.NUREMA.REC.1401.063

Public title

Minerva immobilization

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

men 40 to 18 ages Cervical vertebrae without a history
of previous injury

Exclusion criteria:

Absence of pain, muscle spasm, arthritis, neurological
disease and any history of neck surgery Absence of
systematic skin or skeletal damage that makes it
possible to wear a brace

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **29**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Efsan University of Medical
Sciences

Street address

Hezargarib Blvd., Efsan city., Efsan university of
medical science

City

Efsan

Province

Isfahan

Postal code

81746-73461

Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Healthy people

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The primary message is the range of motion of the neck

Timepoint

The immediate effect of wearing the first brace is
checked, and the immediate effect of the second brace is
checked thirty minutes after the first brace on the same
day

Method of measurement

he range of motion of the neck is measured in degrees
by a three-dimensional motion analysis device. This
device follows the movements of night vision markers by
shining infrared rays on them and measures the angles.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: rigid brace: The Minerva used in this
research is a one-size adult Minerva manufactured by Kia
Medical Company, which consists of two body shells in
the front and back of the thorax.

Category

Treatment - Devices

2

Description

Intervention group: The second intervention is performed
on the same group after thirty . Foam brace: This brace
is very similar to Yale brace. Yale's original brace is a
lightweight brace used to stabilize the cervical spine, this
brace is a kind of long polypropylene load-bearing
philadelphia that extends anteriorly and posteriorly to
the thoracic region, and an anterior chest strap. and
makes the rear. links to In Minerva foam brace, there are
changes compared to Yale brace, in that the back
support part is longer and a forehead strap is added to it.
The inside of the polypropylene is covered with foam.
This brace is made by Pouyan Mehr clinic.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazar Jarib Street, Isfahan University of Medical Sciences and Health Services, Faculty of Rehabilit

Full name of responsible person

Hossein AsiaiMehr

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Hazar Jarib Street, Isfahan University of Medical Sciences and Health Services, Faculty of Rehabilitation Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4, Research and Technology Vice-Chancellor

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Asiaimehr

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthosis Prosthetic

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Person responsible for scientific inquiries

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Orthosis and prosthesis

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Person responsible for updating data

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Other areas of specialty/work

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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

No - There is not 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

No - There is not 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

All the studied data, such as degrees of neck movements, are published. the title is cervical range of motion

When the data will become available and for how long

The access starts two months after printing and the date of access is unlimited.

To whom data/document is available

The reduction effect of wearing a brace is measured in this study

Under which criteria data/document could be used

Analysis of the range of motion of the neck can be accessed by the software. Statistical analyzes can also be accessed

From where data/document is obtainable

09387324996 o.stufan@gmail.com Alireza Khalili

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

Information will be given after a call or email a week after the request

Comments