Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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 Efahan University of Medical Sciences
Street address
Hezargerib Blvd., Esfahan city., Esfahan university of medical science
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2022-08-20, 1401/05/29
Ethics committee reference number
IR.MUI.NUREMA.REC.1401.063

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

Street address
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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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Orthosis and prosthesis

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Person responsible for updating data

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Other areas of specialty/work
Orthosis and prosthesis

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

Comments