

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of medial longitudinal arch support with and without night Knee-Ankle-Foot orthosis (KAFO) on changes and correction of genu valgum in children less than ten years old

Protocol summary

Study aim

Comparison of the effect of night knee-ankle-foot orthosis (KAFO) with medial longitudinal arch support with medial longitudinal arch support alone in correction and changes of genu valgum in children under 10 years

Design

The present study is a clinical trial with a control group, with parallel, non-blind, randomized groups by Hidden sealed envelope method, study phase 2-3 where the sample size is determined by the pilot study.

Settings and conduct

In this study, children with genu valgum who are referred to the physical medicine and rehabilitation center of Firoozgar and Rasoul Akram hospitals are evaluated. Patients are randomly divided into two groups by Hidden sealed envelope method. In initial Alignment view XRay, the angles of the medial proximal tibia, lateral distal femur, Intercondylar distance, and lower extremity length are measured. For six months, patients in the first group, in addition to night orthosis, are prescribed a medial longitudinal arch support, and the second group is prescribed a medial longitudinal arch support. After six months, the Alignment View XRay is taken again and the mentioned angles are measured.

Participants/Inclusion and exclusion criteria

Children under 10 years with non-physiological genu valgum with or without a flexible flat foot are imported. Genu valgum caused by neuromuscular diseases or fractures are removed.

Intervention groups

Intervention 1 includes: night knee-ankle-foot orthosis (KAFO) with medial longitudinal arch support Intervention 2 includes: medial longitudinal arch support alone.

Main outcome variables

Medial proximal tibial angles, lateral distal femur, Intercondylar distance, and lower extremity lengths are measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170910036107N7**

Registration date: **2021-09-28, 1400/07/06**

Registration timing: **prospective**

Last update: **2021-09-28, 1400/07/06**

Update count: **0**

Registration date

2021-09-28, 1400/07/06

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Name of ethics committee Ethics Committee of Iran University of Medical Sciences
Scientific title Comparison of the effect of medial longitudinal arch support with and without night Knee-Ankle-Foot orthosis (KAFO) on changes and correction of genu valgum in children less than ten years old	Street address Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran, Iran
Public title Comparison of the effect of medial longitudinal arch support with and without night Knee-Ankle-Foot orthosis (KAFO) on changes and correction of genu valgum in children less than ten years old	City Tehran
Purpose Treatment	Province Tehran
Inclusion/Exclusion criteria Inclusion criteria: Children 10 years and younger Angular deformity of the valgus around the knee in the coronal plane for no other reason than deformity such as trauma, or any neuromuscular disease Exclusion criteria: inflexible flat foot Physiological genu valgum History of lower limb bone surgery	Postal code ۱۴۳۹۶۱۴۵۳۵
Age To 10 years old	Approval date 2021-06-22, 1400/04/01
Gender Both	Ethics committee reference number IR.IUMS.FMD.REC.1400.222
Phase N/A	Health conditions studied
Groups that have been masked No information	1
Sample size Target sample size: 20	Description of health condition studied Genu valgum
Randomization (investigator's opinion) Randomized	ICD-10 code M21.06
Randomization description Patients are randomly divided into two groups by Hidden sealed envelope randomization method. In such a way, an equal number of interventions are written in the same size sheets and the sheet is folded in such a way that the type of intervention is not clear. If the patient is selected for the study, parents will randomly pick up a sheet of envelope indicating the type of intervention.	ICD-10 code description Valgus deformity, not elsewhere classified, knee
Blinding (investigator's opinion) Not blinded	Primary outcomes
Blinding description	1
Placebo Not used	Description Proximal medial tibia angle
Assignment Parallel	Timepoint Before the intervention and 6 months after treatment
Other design features	Method of measurement X-ray
Secondary Ids empty	2
Ethics committees	Description Lateral femoral distal angle
1	Timepoint Before the intervention and 6 months after treatment
Ethics committee	Method of measurement X-ray
	3
	Description Intercondylar distance
	Timepoint فاصله اینترکوندیلار
	Method of measurement X-ray
	4
	Description Lower limb length
	Timepoint

Before the intervention and 6 months after treatment

Method of measurement

X-ray

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: knight Knee-Ankle-Foot orthosis (KAFO) with medial longitudinal arch support insole. Knight Knee-Ankle-Foot orthosis (KAFO) is made by measuring method. It is measured from the inside of the gluteal to the knee, from the knee to the ankle, and the length of each person's foot. Knight Knee-Ankle-Foot orthosis (KAFO) has a cuff in the thigh area and a Ankle-Foot orthosis (AFO) made of polyethylene, which are connected by two steel rods on both sides. The mechanism of action of knight Knee-Ankle-Foot orthosis (KAFO) is a system of three pressure points, two points of pressure on the outside of the foot and above and below the knee joint and one point on the opposite side in the area of the knee joint. In this orthosis, the knee is placed at a zero degree angle without movement and the ankle is placed at a 90 degree angle. The insole is made of polyurethane (PU) with medial longitudinal arch support, by scanning the feet of individuals. To make this insole Computer-aided design (CAD) and Computer-aided manufacturing (CAM) method is used.

Category

Treatment - Devices

2

Description

Second intervention group: Medial longitudinal arch support insole. The insole is made of polyurethane (PU) with medial longitudinal arch support, by scanning the feet of individuals. To make this insole Computer-aided design (CAD) and Computer-aided manufacturing (CAM) method is used.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar hospital

Full name of responsible person

Narges Mahdizade

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2

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Sponsors / Funding sources

1

Sponsor

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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

Iran 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable