

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Designing and fabrication an ergonomic insole to correct foot posture in pregnant women.

Protocol summary

Summary

Purpose of this study: Designing And Fabrication An Ergonomic Insole To Correct Foot Posture In Pregnant Women. Study design: Randomized to intervention and control groups. Methodology: A) The study population: - The Inclusion criteria: Pregnant women who are in the age range 18-32 and are in week 20 of pregnancy. -The exclusion criteria: Those with congenital musculoskeletal disorders, surgery on the leg, and any kinds of living and working conditions that have an impact on the foot and posture. - Sample size: 50 Pregnant women B- Intervention or interventions Of studied: Providing an ergonomic insoles for women C- Time of intervention: 20 Weeks of pregnancy until 36 weeks (3 months) D- Primary outcome or consequences of the study: Supporting foot arch. Improving foot posture and reducing back pain and Expected to reduce foot pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021121044N1**
Registration date: **2015-05-10, 1394/02/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Shaghayegh Koohi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, .Shiraz University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and fabrication an ergonomic insole to correct foot posture in pregnant women.

Public title

Designing and fabrication an ergonomic insole to correct foot posture in pregnant women.

Purpose

Prevention

Inclusion/Exclusion criteria

The Inclusion criteria: pregnant women who are in the age range of 18-32 and are in the 20th week of pregnancy. The exclusion criteria: those with congenital musculoskeletal disorders, surgery on the leg, and any condition that have an impact on the foot and posture.

Age

From **18 years** old to **32 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

delete

Secondary trial Id

delete

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of shiraz university of medical sciences

Street address

Health faculty, Fath-Al-Mobin alley, Zahra Ave, Shiraz

City

Shiraz

Postal code

Approval date

2014-04-09, 1393/01/20

Ethics committee reference number

CT-9373-7293

Health conditions studied

1

Description of health condition studied

Foot posture in pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

effect on longitudinal arch of foot

Timepoint

3 month

Method of measurement

Foot posture index, Fiess line

2

Description

Supporting longitudinal arch of foot

Timepoint

3 month

Method of measurement

Foot posture index, Fiess line

3

Description

Effect on rotation of heels during pregnancy

Timepoint

3 month

Method of measurement

Foot posture index, Fiess line

Secondary outcomes

1

Description

Effect on backache during pregnancy

Timepoint

3 month

Method of measurement

Foot posture index, Fiess line

2

Description

Effect on back pain after pregnancy

Timepoint

3 month

Method of measurement

Foot posture index, Fiess line

3

Description

Effect on kneeache after pregnancy

Timepoint

3 month

Method of measurement

Foot posture index, Fiess line

4

Description

Effect on kneeache during pregnancy

Timepoint

3 month

Method of measurement

Foot posture index, Fiess line

Intervention groups

1

Description

Intervention group: Assessment of Foot posture in pregnant women at 20 weeks of pregnancy and then giving them medical insoles made of leather and foam designed for pregnant women and Finally, Assessment feet of women after 3 months.

Category

Other

2

Description

Control: No action, Evaluation of foot in pregnant women in 20 weeks of pregnancy and then assess the feet of women within 3 months.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez clinic

Full name of responsible person

Dr. Samsami

Street address

Hafez Hospital, Chamran Blvd, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, .Shiraz University of Medical Sciences

Full name of responsible person

Dr.Basir Hashemi, Manager of Research and assessment of investigations

Street address

Vice chancellor for research: The seventh floor, Central Building of shiraz university of medical sciences, next to the Red Cross, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, .Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences, School of Health

Full name of responsible person

Shaghayegh Koochi

Position

Student, Msd Ergonomic

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Associate Professor

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty