

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of kinesio tape on low back pain and performance dysfunction in pregnant women presenting to comprehensive health centers

Protocol summary

Low back pain, performance dysfunction

Study aim

If Kinesio tape can reduce the symptoms of low back pain during pregnancy and improve the function, it can be recommended as a cheap and uncomplicated treatment.

Design

A double-blind clinical trial with a control group, a sample size of 80 people, simple random

Settings and conduct

A Kinesio tape with a length of approximately 20 cm and a width of 5 cm with a 50% stretch is placed vertically from the bottom of the pain area upward at a distance of 2 cm from the spine on a clean, non-greasy and lotion free skin. Another tape is placed parallel to the first one on the other side of the spine at a distance of 4 cm from the first tape. Another tape is transversely placed with a 70% stretch in the sacroiliac region. Another tape without stretching is inserted on the abdominal region to reduce the pressure of the lumbar vertebrae and support the abdominal muscles. Participants and evaluators are blinded to the sampling.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Written informed consent Age:18-40 years old Being pregnant in the second or third trimester (gestational age of 18-32 week), Mild to moderate low back pain (Visual analogue scale 1-7) No known or suspected orthopedic or rheumatologic disorders including scoliosis, spine injuries, rheumatoid arthritis No known intervertebral discopathy No skin lesion in the lumbosacral area No vertebral anomaly No skin allergy Singleton pregnancy No history of low back pain prior to pregnancy No addiction No NSAID consumption No history of other non-medical treatments Exclusion criteria: Allergy to kinesio tape kinesio tape coming off before the fifth day Any uncontrolled medical condition

Intervention groups

The intervention group receives Kinesio tape. The control group receives leukoplast tape.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181210041911N1**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Seyede maryam Lotfipour rafsanjany

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

m.lotfi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-18, 1397/10/28

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of kinesiio tape on low back pain and performance dysfunction in pregnant women presenting to comprehensive health centers
Public title	The effect of kinesiio tape on low back pain and performance dysfunction in pregnant women
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Written informed consent Age:18-40 years old Being pregnant in the second or third trimester (gestational age of 18-32 week) Mild to moderate low back pain (Visual analogue scale 1-7) No known or suspected orthopedic or rheumatologic disorders including scoliosis, spine injuries,rheumatoid arthritis No known intervertebral discopathy No skin lesion in the lumbosacral area No vertebral anomaly NO skin allergy Singleton pregnancy NO history of low back pain prior to pregnancy No addiction No NSAID consumption No history of other non-medical treatments Exclusion criteria: Allergy to kinesiio tape kinesiio tape coming off before the fifth day Any uncontrolled medical condition Severe low back pain (Visual analogue scale 7-10) Unwillingness to continue the study
Age	From 18 years old to 40 years old
Gender	Female
Phase	N/A
Groups that have been masked	• Participant • Outcome assessor
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization by tossing a coin (to determine the first group)
Blinding (investigator's opinion)	Double blinded
Blinding description	Participants and outcome evaluators are blinded to sample ellocation of the groups
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of rafsanjan university of medical sciences
Street address	Rafsanjan-Imam Ali Blvd. - Central Organization
City	Rafsanjan
Province	Kerman
Postal code	7717933777
Approval date	2019-01-18, 1397/10/28
Ethics committee reference number	IR.RUMS.REC.1397.183
Health conditions studied	
1	
Description of health condition studied	Low back pain and Performance disability of the second and third trimester of pregnancy
ICD-10 code	O26.8
ICD-10 code description	Other specified pregnancy related conditions
Primary outcomes	
1	
Description	Low back pain score with visual analogue scale(vas)
Timepoint	Measurement of low back pain before intervention and 1.2.7 and 14 days after intervention
Method of measurement	Visual analogue scale
Secondary outcomes	
1	
Description	Functional disability score with Roland morris disability questionnaire
Timepoint	Measurement of disability before intervention and 7.14 days after intervention
Method of measurement	Roland morris disability questionnaire
Intervention groups	

1

Description

The intervention group: Kinesio adhesive tape, 5-meter roll and 5 cm wide (made in Korea). two strips of 20 centimeters with a width of 5 centimeters are placed with medium stretching from the bottom of the pain area upwards on the sides of the spine, another with 70% stretching is attached transversally to the sacroiliac joint. To reduce the pressure of the lumbar vertebrae and support the abdominal muscles, a tape is also inserted on the stomach without stretching. The tapes are removed on day 5 by the participant.

Category

Treatment - Other

2

Description

the control group: Leukoplast tape, 5 m long and 5 cm wide (made in China). Two 20 cm tape strips with a width of 5 cm are placed from the bottom of the pain area upward on the sides of the spine. Another tape is transversely attached to the sacroiliac joint to reduce the pressure of the lumbar vertebrae and support the abdominal muscles. A tape is also inserted on the abdomen. The tapes are removed on day 5 by the participant.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health center no. five

Full name of responsible person

Tayebeh Alishahi

Street address

Kargar street

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2

Recruitment center

Name of recruitment center

Comprehensive health center no. one

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Tayebeh alishahi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Nursing Ave, Motahhari Blvd Faculty of Nursing,
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Academic instructor

Latest degree

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Person responsible for updating data

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Position

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Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available