Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2021

Comparing the effect of Kinesio Taping (KT) and Placebo Taping (P) on Lateral Abdominal Wall and Lumbar Multifidus Muscles Thickness Change in Subjects With Non-Specific Chronic Low Back Pain

Protocol summary

Study aim
Effect of Kinesio Taping on Thickness Changes of Lateral Abdominal and Multifidus Muscles in Non-Specific Chronic Low Back Pain

Design
Randomized control trial, with two parallel groups and double blinded

Settings and conduct
This research is a double-blind, control clinical trial. This research is carried out at the Tehran University of Medical Sciences Rehabilitation Faculty Research Center. In this research, a pilot and reliability study will be conducted than main research will be done. Subjects enter the research after completing the consent form, understanding of how to do the research and having the inclusion criteria . Individual information is collected by questionnaire. After the randomization, the subject is placed in one of the intervention or control groups. Ultrasound findings from abdominal and lumbar muscles are collected before intervention. For the intervention group, the kinesio taping of the lumbar and abdominal muscles are used, and the placebo taping is used for the control group. After 72 hours, reassessment takes place. In this study, participants, data collectors and data analyzers are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Subjects aged 25 - 55 years with history of low back pain Lasting more than 3 Pain intensity between 4-7 of the Visual Analog Scale (VAS) Exclusion criteria: Allergic sign of kinesio taping Taking painkiller during research

Intervention groups
In the intervention group, kinesio taping of the lumbar and abdominal muscles is performed and placebo taping is used for the control group.

Main outcome variables
Pain intensity; Disability level; Muscle Thickness change (transvers abdominis (TrA), internal oblique (IO), external oblique (EO) and multifidus (MF)) in both sides, left and right

General information

Reason for update
Change the number of groups, outcome measures and end of the study

Acronym

IRCT registration information
IRCT registration number: **IRCT20090301001722N20**
Registration date: **2018-05-21, 1397/02/31**
Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**
Update count: **1**

Registration date
2018-05-21, 1397/02/31

Registrant information

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Mohammad-Reza Hadian

Name of organization / entity
Tehran University of Medical Sciences, Faculty of Rehabilitation

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-05, 1397/03/15

Expected recruitment end date
2018-12-06, 1397/09/15
Actual recruitment start date
2018-07-06, 1397/04/15
Actual recruitment end date
2018-12-21, 1397/09/30
Trial completion date
2018-12-21, 1397/09/30

Scientific title
Comparing the effect of Kinesio Taping (KT) and Placebo Taping (P) on Lateral Abdominal Wall and Lumbar Multifidus Muscles Thickness Change in Subjects With Non-Specific Chronic Low Back Pain

Public title
Effect of Kinesio Taping (KT) on Abdominal and Lumbar Muscles Thickness Change in Chronic Low Back Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Lasting more than 3 months and radiating no further than the buttock Pain intensity between 4-7 of the Visual Analog Scale (VAS) No open wounds and skin diseases No previous history of neurological disease No previous history of sciatica or other radicular involvement No previous history of disc herniation No previous history of spine surgery No previous history of rheumatic diseases and diabetes No previous history of mental disease No pregnancy No previous history of neuromascular diseases
Exclusion criteria:
Allergic sign of kinesio taping Taking painkiller during research
Age
From **25 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is used in the form of a random number table. Participants will be randomly assigned to their treatment groups according to the numbers obtained from the table, KT group (00-30), placebo (30-60) and control group or without tape (60-90). The allocation of the subjects will be concealed by using sequentially numbered, sealed and opaque envelopes. On the first day of treatment, the envelope allocated will be opened by participant.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants will be blinded to the study hypotheses (ie, KT versus Placebo or control). Due to the nature of the interventions it was not be possible to blind the researcher. So, the first researcher will apply the typing method, while the second researcher will be blind as the data evaluator. Data analyzer is also blind who is first researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Keshavarz bolvar, Ghods Ave, 6 floor, Tehran University of Medical Science building
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-05-29, 1396/03/08
Ethics committee reference number
IR.TUMS.FNM.REC.1396.2448

Health conditions studied

1

Description of health condition studied
Non Specific Chronic Low Back Pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain intensity
Timepoint
Before and 72 hours after intervention
Method of measurement

Visual Analogue Scale (VAS) and Short-form McGill Pain Questionnaire

2

Description
Disability index
Timepoint
Before and 72 hours after intervention
Method of measurement
Oswestry disability Questionnaire

3

Description
contraction ratio
Timepoint
Before and 72 hours after intervention
Method of measurement
In formula

4

Description
resting and contracted thickness
Timepoint
Before and 72 hours after intervention
Method of measurement
Using an ultrasound cursor, the thickness of each muscle is determined in millimetres

Secondary outcomes

1

Description
Lumbar proprioception
Timepoint
Before and 72 hours
Method of measurement
Measurements of lumbar repositioning error (45 and 60 degree of flexion and 15 degree of extension) using double bubble inclinometer

Intervention groups

1

Description
Intervention group: Kinesio taping of the lumbar and abdominal muscles is performed
Category
Treatment - Other

2

Description
Placebo group: Placebo taping is used for the lumbar and abdominal muscles
Category
Placebo

3

Description
Control group: without taping
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation cilinic of Tehran University of Medical Science
Full name of responsible person
Dr Mohsen Mir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
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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
All rights of this research belongs to TUMS.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable