

# 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

###### Name

Mohammad-Reza Hadian

###### Name of organization / entity

Tehran University of Medical Sciences, Faculty of Rehabilitation

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7753 6134

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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 neuromuscular 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 possible to blind the researcher. So, the first researcher will apply the taping 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

#### **Street address**

Engheleb Ave

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abbasipt85@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Amir Ali Sohrabpour

#### **Street address**

Keshavarz Blvd, Tehran University of Medical Science

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aasohrabpour@tums.ac.ir

#### **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

**Full name of responsible person**

Mohammad Reza Hadian

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Soheila Abbasi

**Position**

PhD Candidate

**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**

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