

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Ipsilateral Sacroiliac dysfunction among (Right/Left-hand drive) taxi drivers and effect of sacroiliac belt on muscular activity during sit to unilateral stand task.

Protocol summary

Study aim

1. To find the ipsilateral SIJP among the taxi drivers.
2. To find relation between the driving side and the side of involvement of the SIJP.
3. Predisposing factors causing SIJP in the drivers.

Design

Randomized clinical controlled trial (RCT)

Settings and conduct

600 Taxi drivers from Iran & 600 from Pakistan would be recruited by Simple Random Sampling (SRS). A valid questionnaire (Oswestry Disability Index- Iranian Version, Roland-Morris Disability Index- Iranian Version, the Quebec Back Pain Disability Scale with an additional self-administered questionnaire having socio-demographic factors, work characteristics and dysfunction explanation, designed for this study would be filled by the researcher while asking the questions regarding low back pain from left hand drive drivers from Iran and the Urdu version of above mentioned questionnaires would be used for right hand drive drivers in Pakistan. In the second phase of the research. EMG would be performed on the SIJP & healthy group.

Participants/Inclusion and exclusion criteria

Male taxi drivers aged between 20-60 years with work experience of more than one year and willing to cooperate will be included in initial phase of the study. For EMG recording, SIJP of at least 2 months pain in joint, no radiation of pain towards lower limb, diagnosed by 3 positive sacroiliac provocative tests, having no postural dysfunction or limb length discrepancy would be selected. Healthy group for EMG recording would be selected on the basis of no previous pain history in SIJ, having normal active straight leg raising (ASLR) test and with no congenital anomaly.

Intervention groups

Sacroiliac Belt

Main outcome variables

1. Pain
2. Function
3. RMS
4. Muscle Activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090301001722N17**

Registration date: **2018-02-09, 1396/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

Samira Karimpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences- International Campus

Expected recruitment start date

2017-09-15, 1396/06/24

Expected recruitment end date

2018-03-15, 1396/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ipsilateral Sacroiliac dysfunction among (Right/Left-hand drive) taxi drivers and effect of sacroiliac belt on muscular activity during sit to unilateral stand task.

Public title

Ipsilateral Sacroiliac dysfunction among (Right/Left-hand drive) taxi drivers and effect of sacroiliac belt on muscular activity during sit to unilateral stand task.

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Male taxi drivers Aged between 20-60 years Work experience of more than one year willing to cooperate

Exclusion criteria:

Having history of surgery Acute pathological condition Radiating pain toward lower limb Any limb length discrepancy

AgeFrom **20 years** old to **60 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Investigator

Sample sizeTarget sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right & left sides (Or healthy & affected in patients) of each individual would be investigated

Randomization (investigator's opinion)

Randomized

Randomization description

The examiner will remain blind about the low back condition who will perform sacroiliac provocative test. During EMG, the investigator will also be bling about the side of involvement of the sacroiliac Joint and low back pain.

Blinding (investigator's opinion)

Single blinded

Blinding description

The examiner will remain blind about the low back condition who will perform sacroiliac provocative test. During EMG, the investigator will also be bling about the side of involvement of the sacroiliac Joint and low back pain.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences (TUMS)

Street address

School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2017-09-11, 1396/06/20

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3443

Health conditions studied**1****Description of health condition studied**

Sacroiliac Joint Dysfunction

ICD-10 code

M99.04

ICD-10 code description

Musculoskeletal disorders - Segmental and somatic dysfunction of sacral region

Primary outcomes**1****Description**

PAIN

Timepoint

Before & after Treatment (Immediate effect & Prolong Effect after one month)

Method of measurement

Numeric Pain Rating Scale (NPRS)

2**Description**

Integrated EMG

Timepoint

Before and after Treatment

Method of measurement

Surface EMG by Biometrics (Ltd) data Log

3**Description**

Root mean square (RMS)
Timepoint
Before and after Treatment
Method of measurement
Surface EMG by Biometrics (Ltd) data Log

4

Description
Time to peak
Timepoint
Before and after Treatment
Method of measurement
Surface EMG by Biometrics (Ltd) data Log

5

Description
Duration of the muscle activity
Timepoint
Before and after Treatment
Method of measurement
Surface EMG by Biometrics (Ltd) data Log

6

Description
Premotor Time
Timepoint
Before and after Treatment
Method of measurement
Surface EMG by Biometrics (Ltd) data Log

Secondary outcomes

1

Description
Function
Timepoint
Before and after Treatment
Method of measurement
Modified Oswestry Disability

Intervention groups

1

Description
Intervention group(A): Before Treatment; EMG would be performed on this group before the application of Sacroiliac belt.
Category
Treatment - Other

2

Description
Intervention group(B): After Treatment; EMG would be performed on this group after the application of Sacroiliac belt.
Category

Treatment - Other

3

Description
Control group:Based on methodology, EMG would be performed on this healthy group without performing any treatment.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation,Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad-Reza Hadian Rasanani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran 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
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 (TUMS)-
International Campus
Full name of responsible person
Dr.Mohammad-Reza Hadian Rasanani
Position
Professor
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Other areas of specialty/work
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Person responsible for updating data

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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

As per consent form, Researcher was obliged to keep the
participants information confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Study Protocol: It would be available in the published article & thesis in the library
Statistical Analysis Plan: It would be available in the published article & thesis in the library
Informed Consent Form: It would be available in the thesis in the library
Clinical Study Report: In the form of published articles or report

When the data will become available and for how**long**

For Ever

To whom data/document is available

For All

Under which criteria data/document could be used

According to the rules of journal and library

From where data/document is obtainable

Journals & Library in the institute

What processes are involved for a request to access data/document

Contact to journal or researcher

Comments