

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 3939

##### Email address

hadianrs@sina.tums.ac.ir

##### 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

**Age**

From **20 years** old to **60 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Investigator

**Sample size**

Target 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

**Street address**

School of Rehabilitation, Tehran University of Medical Sciences. Enghelab Ave. Pich-Shemiran

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**Postal code**

1148965111

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+98 21 8891 3469

**Email**

hadianrasan@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Amirali Sohrabi

**Street address**

Tehran University of Medical Sciences Keshavarz Blvd, Kods street Tehran Tehran Iran, Islamic Republic Of 14167

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**Email**

tums\_edu@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 (TUMS)-  
International Campus

**Full name of responsible person**

Dr.Mohammad-Reza Hadian Rasanani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

School of Rehabilitation of Tehran University of  
Medical Sciences, Piche Shemiran, Enghelab Ave,  
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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad-Reza Hadian

**Position**

Professor, School of Rehabilitation, Tehran University  
of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**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**