

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Monopolar Electrocautery versus Scalpel on paraspinal muscle dissections: The effect on electrodiagnostic study

#### Protocol summary

##### Summary

The aim of this study is to evaluate the paraspinal muscle dissection safe method. This study is double-blind interventional study. Every patient is both case and control. Inclusion criteria: Patients with a fractured spine who are candidate for posterior segmental fixation surgery. Exclusion criteria: Lack of consent to participate in the study; Patients with neurological deficit before surgery; Hemodynamic instability and etc. interventions of the study are Paraspinal muscle dissection with Monopolar Electrocautery in right side and Paraspinal muscle dissection with a Scalpel in left side. The main outcome variable is F-wave latency in preoperation and postoperation over the three lower extremity nerves (Femoral nerve, Tibial nerve and Peroneal nerve).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017041233383N1**

Registration date: **2017-06-17, 1396/03/27**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-06-17, 1396/03/27

##### Registrant information

##### Name

Keramat Saeidi

##### Name of organization / entity

Neurosurgery resident

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3277 7502

##### Email address

a.nazemirafie@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2017-12-22, 1396/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Monopolar Electrocautery versus Scalpel on paraspinal muscle dissections: The effect on electrodiagnostic study

##### Public title

Effect of Monopolar Electrocautery versus Scalpel

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with a fractured spine who candidates for posterior segmental fixation surgery.

Exclusion criteria: Lack of consent to participate in the study; Patients with significant preoperative paresis; Patients in need of laminectomy, foraminotomy or obvious distraction; Unstable conditions and non-cooperative patients( Critically ill, Incomplete consciousness); Vertebral fractures outside the scope of T10 to S1.

##### Age

No age limit

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 30

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the Arak University of Medical Sciences

##### Street address

Ethics Committee , Arak University of Medical Sciences , Aalam al-Hoda St , Shahid Shirodi Ave , Arak , Iran

##### City

Arak

##### Postal code

3819693345

#### Approval date

2010-08-20, 1389/05/29

#### Ethics committee reference number

9317420

## Health conditions studied

### 1

#### Description of health condition studied

Fractured spine candidates for posterior segmental fixation surgery

#### ICD-10 code

G54.3; G54

#### ICD-10 code description

Thoracic root disorders, Not elsewhere classified;  
Lumbosacral root disorders, Not elsewhere classified

## Primary outcomes

### 1

#### Description

Nerve Conduction Velocity( F-wave latency)

## Timepoint

Before surgery; One day after surgery

## Method of measurement

F-wave latency time in milliseconds by an Electromyogram

## Secondary outcomes

### 1

#### Description

Neurologic deficit

#### Timepoint

Before surgery; One day after surgery

#### Method of measurement

Physical examination: Sensory; Motor; Sphincter

## Intervention groups

### 1

#### Description

The right side paraspinal muscles cut with Monopolar Electrocautery.

#### Category

Treatment - Surgery

### 2

#### Description

The left side paraspinal muscles cut with Scalpel.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Neurosurgery Valiasr Hospital, Arak

##### Full name of responsible person

Keramat Saeidi

##### Street address

Valiasr Hospital , Valiasr Sq, Arak , Iran

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Arak University of Medical Sciences

##### Full name of responsible person

Ali Arash Anooshirvani

##### Street address

Vice President of Research , Arak University of Medical Sciences , Aalam al-Hoda St , Shahid Shirodi

Ave , Arak , Iran

**City**

Arak

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Arak University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Neurosurgery resident of Arak University of Medical Sciences

**Full name of responsible person**

Keramat Saeidi

**Position**

Neurosurgery resident

**Other areas of specialty/work**

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Ali Nazemi Rafie

**Position**

Associate Professor, Department of Neurosurgery

**Other areas of specialty/work**

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Neurosurgery resident of Arak University of Medical Sciences

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**Postal code**

**Phone**

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**Email**

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**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*