

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

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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

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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

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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Person responsible for scientific inquiries

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Ali Nazemi Rafie

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Associate Professor, Department of Neurosurgery

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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