Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Street address

Valiasr Hospital , Valiasr Sq, Arak , Iran

City

Arak

Postal code

3816148185

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

ka017sam@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Science

Full name of responsible person

Ali Nazemi Rafie

Position

Associate Professor, Department of Neurosurgery

Other areas of specialty/work

Street address

Valiasr Hospital , Valiasr Sq, Arak , Iran

City

Arak

Postal code

Phone

+98 86 3222 2005

Fax

Email

nazemirafie.ali@gmail.com

Web page address

Person responsible for updating data

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

Street address

Valiasr Hospital , Valiasr Sq, Arak , Iran

City

Arak

Postal code

Phone

Fax

Email

ka017sam@gmail.com

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