

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Feb 2026

Safety and Efficacy Assessment of Combination of Artificial Dura and Umbilical Cord and Placenta Mesenchymal Stem Cell-Derived Exosomes in Patients with Acute, Sub-acute and Chronic Complete Spinal Cord Injury: A Single-blinded Controlled Clinical Trial

Protocol summary

Study aim

Assessment of the combination of artificial dura and umbilical cord and placenta-derived mesenchymal stem cell exosomes in patients with complete spinal cord injury.

Design

This study is a non-randomized, controlled, four-arm parallel-group, phase 2 trial on 20 patients.

Settings and conduct

This study includes 20 patients having acute complete spinal cord injury. All the patients will be followed their standard spinal surgery in the hospital and assigned non-randomly in four groups to receive new treatments. Patients will be assessed in terms of the study outcomes before treatment, 3, 6, and 12 months after injury.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Traumatic spinal cord injury 36 months have passed since the spinal cord injury Complete spinal cord injury (class A in ASIA scale) Written informed consent Exclusion criteria: History of previous spinal surgery Amputation Having underlying diseases affecting the diagnosis and treatment process (such as diabetes mellitus, osteopenia, spinal cord injury, etc.)

Intervention groups

Patients in the present study will be non-randomly assigned to three groups including the patients treated with artificial dura and exosome group, the patients treated with artificial dura group, patients treated with exosome alone, and the control group which receives the standard therapy.

Main outcome variables

Primary outcomes: Sensory and motor scores of the American Spinal Injury Association Impairment Scale, mean of the Spinal Cord Independence Measure III scores of patients.

General information

Reason for update

According to the definition of the inclusion criteria, the patients who were initially included in the study had been up to six months since their injury, unfortunately, at the beginning of the study, only the word acute was written in the definitions of the protocol title, which has been corrected. On the other hand, to include patients with chronic phases, the time interval from the injury was changed to 36 months. Due to the possible effects of exosome, we needed to add the exosome treatment group alone so that the clinical trial does not suffer from problems in terms of methodology and results, and the results of other groups can be compared with this group. The source of the exosomes was added and the study population edited.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047277N1**
Registration date: **2020-10-02, 1399/07/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-25, 1402/01/05**

Update count: **2**

Registration date

2020-10-02, 1399/07/11

Registrant information

Name

saeed oraee yezdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

saeed_o_yezdani@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-02, 1399/06/12

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and Efficacy Assessment of Combination of Artificial Dura and Umbilical Cord and Placenta Mesenchymal Stem Cell-Derived Exosomes in Patients with Acute, Sub-acute and Chronic Complete Spinal Cord Injury: A Single-blinded Controlled Clinical Trial

Public title

Effect of the combination of artificial dura and umbilical cord and placenta mesenchymal stem cell-derived exosomes in patients with complete spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Traumatic spinal cord injury Time from injury up to 36 months Complete spinal cord injury (class A in ASIA scale) Written informed consent

Exclusion criteria:

History of previous spinal surgery Amputation Having underlying diseases affecting the diagnosis and treatment process (such as: diabetes mellitus, osteopenia, spinal cord injury, etc.)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran

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Province

Tehran

Postal code

1985717443

Approval date

2020-09-01, 1399/06/11

Ethics committee reference number

IR.SBMU.MSP.REC.1399.235

Health conditions studied

1

Description of health condition studied

Complete spinal cord injury

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes

1

Description

Motor score of the American Spinal Injury Association Impairment Scale

Timepoint

Before treatment, 3, 6, and 12 months after injury.

Method of measurement

Physical examination

2

Description

Sensory score of the American Spinal Injury Association Impairment Scale

Timepoint

Before treatment, 3, 6, and 12 months after injury.

Method of measurement

Physical examination

3

Description

Mean of the "Spinal Cord Independence Measure III" scores of patients

Timepoint

Before treatment, 3, 6, and 12 months after injury.

Method of measurement

Spinal Cord Independence Measure III questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients underwent spinal decompression surgery in the injured area and the patient's dura will be repaired by artificial dura made of polyethylene terephthalate, then pre-prepared umbilical cord and placenta-derived mesenchymal stem cell exosomes were injected in the injury area.

Category

Treatment - Other

2

Description

Intervention group: In this group, patients underwent spinal decompression surgery in the injured area and the patient's dura will be repaired by artificial dura made of polyethylene terephthalate.

Category

Treatment - Other

3

Description

Control group: In this group, patients underwent standard spinal decompression surgery in the injured area and standard physiotherapy will be prescribed for him.

Category

Treatment - Other

4

Description

Intervention group: In this group, patients underwent standard spine decompression surgery in the injured area, and umbilical cord and placenta-derived mesenchymal stem cell exosomes were injected in each patient.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Saeed Oraee Yazdani

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Shohadaye Tajrish hospital, Tajrish Square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadhosein Akhlaghasand

Position

Research Associate

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

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Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

through email request

When the data will become available and for how long

12 month

To whom data/document is available

Principal investigator of other clinical trials

Under which criteria data/document could be used

official request

From where data/document is obtainable

direct request to email

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

evaluation of the validity of the applicant

Comments