Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Sep 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 yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor
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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 Akhlaghpasand

Position
Research Associate

Latest degree
Medical doctor

Other areas of specialty/work
Neuroscience

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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