

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Apr 2019

Evaluation of the efficacy of allogeneic umbilical cord derived hematopoietic stem cells and mesenchymal stromal cells in patients with spastic cerebral palsy on developmental function , A Clinical trial phase 2

Protocol summary

Summary

Cerebral palsy (CP) consisted of a group of nonprogressive disorders of brain injuries . and is one of the major problems of pediatric neurology and at the present time there is no standard medical or surgical treatment for it .Stem cell therapy is one of a new and hopeful therapeutic methods of CP .This study designed for the evaluation of therapeutic effects of intrathecal hematopoietic and mesenchymal stem cells derived from allogenic umbilical cord in improvement of developmental functions of spastic CP patients between 4-14 years old . Developmental conditions consisted of GMFM88 , GMFCS and Denver and spasticity according to Ashworth scale and brain imaging findings documented at the start and during the study period . The patients referred to neurology clinic of Children's Medical Center . Suitable cases selected from patients with remarkable cerebral damage of non congenital origin in imaging .If parents after awareness of etiology and study design and even probable adverse effects have a consent , recruited . 108 cases will be recruited and randomly divided to 3 groups of 36 cases : hematopoietic stem cells derived from allogenic umbilical cord , Mesenchymal cells derived from allogenic umbilical cord and control group without injection and appearance simulating lumbar puncture without awareness of the patients and evaluators .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706176907N13**

Registration date: **2017-07-12, 1396/04/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-12, 1396/04/21

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6612 9252

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences , Social welfare organization of Iran,Royan stem cell Technology , Hormozgn University of Medical Sciences, Stem cell iranian science and technolgy institute

Expected recruitment start date

2017-09-23, 1396/07/01

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

Evaluation of the efficacy of allogeneic umbilical cord derived hematopoietic stem cells and mesenchymal stromal cells in patients with spastic cerebral palsy on developmental function , A Clinical trial phase 2

Public title

effectes of umbilical blood stem cells injection in the treatment of children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : 1-known cases of spastic cerebral palsy(diplegic, hemiplegic or quadriplegic) 2- 4 - 14 years old 3 - Gross motor function classification between 2 -5 4- patient without seizure or with controled seizure

disorder (for patient with suspected seizure EEG must be done before recruitment) 5- evidence of definite abnormal imaging finding compatible with CP that is not congenital 6- informed consent is taken from their parents exclusion criteria: 1- patient with normal brain MRI 2- progressive neurologic diseases (for example leukodystrophy and neurometabolic disease) 3-cortical malformations, genetic disorders such as brain dysgenesis secondary to metabolic causes or infections 4- other types of cerebral palsy including athetoid , atonic , ataxic , and mixed type 5- acute intercurrent infections such as HCV, HBV, HIV 6- malignancies 7- hemorrhagic diathesis , severe anemia (HB less than 8) 8- ventilator dependent pulmonary diseases : pneumonia , respiratory tract infections 9- renal insufficiency 10 - severe liver dysfunction 11- other bone marrow disorders

Age

From **3 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

None

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

در حال حاضر ندارد در حال اقدام هستیم

Secondary trial Id

ندارد

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran university of Medical Sciences

Street address

Keshavarz blvd Ghods street division 6

City

Tehran

Country

Iran (Islamic Republic of)

Postal code**Approval date**

2017-06-06, 1396/03/16

Ethics committee reference number

IR.TUMS.VCRREC.1996.2506

Health conditions studied**1****Description of health condition studied**

spastic cerebral palsy

ICD-10 code

G80.9

ICD-10 code description**Primary outcomes****1****Description**

motor development alteration with GMFM 88 score

Timepoint

begining , 1 month , 3 month ,6 month , 12 month

Method of measurement

questionnaire

2**Description**

improvement of motor function with GMFCS score

Timepoint

begining , 1 month , 3 month ,6 month , 12 month

Method of measurement

questionnaire

3**Description**

spasticity improvement of patients according to Ashworth scale

Timepoint

begining , 1 month , 3 month ,6 month , 12 month

Method of measurement

questionnaire

4**Description**

developmental status according to Denver screening test

Timepoint

begining, 1 month , 3 month ,6 month , 12 month

Method of measurement

questionnaire

Secondary outcomes

1**Description**

Decrement of brain lesion

Timepoint

at onset of study , end of study (1 year)

Method of measurement

MRI , MRS , DTI

2**Description**

fever

Timepoint

24 hours , 48 hours , 72 hours

Method of measurement

axillary thermometer

3**Description**

aseptic meningitis

Timepoint

first 3 days or any time signes ocured

Method of measurement

LP

4**Description**

hyper sensivity reactions

Timepoint

first week of injection

Method of measurement

physical exam

Intervention groups**1****Description**

the group who would be injected intrathecally HSC o rmononuclear hematopoietic stem cell derived from umbilical cord (5 millions per Kg)

Category

Other

2**Description**

the group who would be injected intrathecally MSC or mesenchymal stem cellls derived from umbilical cord (5 million per kg)

Category

Other

3**Description**

attempeting for intrathecal injection simulating lumbar puncture without awareness of patient and evaluators

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children's Medical Center Hospital

Full name of responsible person

anahita majmaa

Street address

end of keshavarz Boulvar Gharib Street children's Medical Center

City

Tehran

Country

Iran (Islamic Republic of)

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

masood yunesian

Street address

Keshavarz Boulvar , Ghods Street , Central organization

City

Tehran

Country

Iran (Islamic Republic of)

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source**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

2**Sponsor****Name of organization / entity**

stem cell iranian science and technolgy institute

Full name of responsible person

Amir ali Hamidie

Street address

Sheykh Bahaae street, Ladane street NUM 20

City

Tehran

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Iran (Islamic Republic of)

Grant name

Grant code / Reference number

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

Title of funding source
stem cell iranian science and technology institute

Proportion provided by this source

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

3

Sponsor

Name of organization / entity
ROYAN stem cell technology

Full name of responsible person
Morteza zarrabi

Street address
No. 24, East Hafez Alley, Bani Hashim Square, Bani Hashim St, Resalat Highway, Tehran, Iran.

City
Tehran

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Iran (Islamic Republic of)

Grant name

Grant code / Reference number

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

Title of funding source
ROYAN stem cell technology

Proportion provided by this source

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

4

Sponsor

Name of organization / entity
Welfare Organization of Iran

Full name of responsible person
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Emam khomeyni square , Shaheed fayazbakhsh street Num 1121

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Country
Iran (Islamic Republic of)

Grant name

Grant code / Reference number

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

Title of funding source
Welfare Organization of Iran

Proportion provided by this source

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

5

Sponsor

Name of organization / entity
Hormozgan University of Medical Sciences

Full name of responsible person
Dr Alireza moaedi

Street address
Shahid mohammadi Hospital , Jomhori eslami Boulvar

City
Bandarabass

Country
Iran (Islamic Republic of)

Grant name

Grant code / Reference number

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

Title of funding source
Hormozgan University of Medical Sciences

Proportion provided by this source

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
Tehran university medical science

Full name of responsible person
Anahita Majmaa

Position
pediatrician

Other areas of specialty/work

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Professor of Pediatric Neurology

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Full name of responsible person

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Position

pediatrician

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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