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Effect of plasma adsorption therapy in amyotrophic lateral sclerosis

Submission date
31/08/2017

Recruitment status
No longer recruiting

Registration date
20/09/2017

Overall study status
Completed

Last Edited
22/09/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Amyotrophic lateral sclerosis (ALS) is a kind of progressive degenerative disease the deteroriates the spinal cord, brain stem and cortical motor neurons (the neurons from the brain). The average survival time from onset to death is 3-5 years. The average age of onset of ALS patients is about 55 years. It has the tendency of being inherited through families in about 5-20% of patients. The disease is not fully understood and there is no effective way to stop the progression of the disease. Plasma adsorption is a new blood purification technology widely used in the treatment of rheumatic diseases (those that affect joints and muscles) and some neurological diseases (diseases that attack the brain and connecting neurons), including myasthenia gravis (muscle weakness that comes and goes), multiple sclerosis and so on. The purpose of this study is to observe the efficacy of PA in the treatment of ALS and to explore its therapeutic mechanism.

Who can participate?
Patients with ALS .

What does the study involve?
Participants received plasma adsorption once a week for three successive times. One and a half times of the plasma volume of a patient is purified for each treatment. Participants are given medication to
prevent anaphylaxis before treatment. Participants are followed up one week after treatment to see if there are any changes in their ALS symptoms.

What are the possible benefits and risks of participating?
Participants may benefit from the improvement of ALS due to plasma adsorption. There are potential risks of allergy, hemorrhage, circulatory disturbance and hemolysis during plasma adsorption. As this procedure have been maturely applied in clinical practice, risks can be controlled very low.

Where is the study run from?
The Third Affiliated Hospital of Southern Medical University (China)

When is the study starting and how long is it expected to run for?
August 2015 to December 2017

Who is funding the study?
Investigator initiated and funded (China)

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZSL201611

Study information

Scientific Title
A Short-term Outcome of Plasma Adsorption Therapy of Amyotrophic Lateral Sclerosis

Study objectives
Plasma adsorption method can improve ALS patients' clinical manifestations, ALSFR-S scores and level of serum superoxide dismutase, serum interleinin, serum creatine kinase and serum lactate dehydrogenase with comparison to before treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee The Third Affiliated Hospital of Southern Medical University China, 29 /08/2015, ref: 201508004

Study design
Single-center one-arm before-and-after study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Amyotrophic Lateral Sclerosis

Interventions
All patients received plasma adsorption once a week for three successive times. For each treatment, blood flow was 80-120mL/min and the slurry velocity was 1.5 L/h. One and a half times of the Plasma volume of a patient was purified for each treatment. 20 mg dexamethasone and 25 mg phenergan were used to prevent anaphylaxis before treatment.
Each participant was planned to be followed up for two years.

The following results of the treatment are evaluated:
1. Changes of clinical manifestations of ALS patients one week after treatment
2. Change of ALSFR-S scores after treatment
3. Changes of serum superoxide dismutase (SOD), serum interleukin -10 (IL-10), serum creatine kinase (CK) and serum lactate dehydrogenase (LDH) after treatment

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Clinical manifestations of ALS patients is measured using the physical examination at one week after treatment
2. Function evaluation is measured using ALSFR-S scores at one week after treatment
3. Serum creatine kinase (CK) and serum lactate dehydrogenase (LDH) at one week after treatment

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Upper and lower motor neuron signs in three regions
2. Any age or gender

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
28

Key exclusion criteria
1. Allergic to membranes or pipelines of plasma separator and adsorber
2. Severe active bleeding or DIC; Systemic circulatory failure which do not respond well to treatment
3. Unstable myocardial or cerebral infarction, intracranial hemorrhage or severe brain edema with cerebral hernia
4. Incoordination due to psychonosema

Date of first enrolment
01/09/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
China

Study participating centre
The Third Affiliated Hospital of Southern Medical University
China
510000

Sponsor information

Organisation
The Third Affiliated Hospital of Southern Medical University

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Sponsor type
Hospital/treatment centre

Website
http: //www.nysy.com.cn/

ROR
https://ror.org/0050r1b65

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We will publish this study in a high-impact target SCINC by one year after our overall trial end date.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and / or analysed during the current study is not expected to be made available due to protecting private information of participants.

IPD sharing plan summary
Not expected to be made available