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Clinical study to assess treatment effects of Cerebrolysin in amyotrophic lateral sclerosis

Submission date
01/12/2023

Recruitment status
No longer recruiting

Registration date
08/01/2024

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Nervous System 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 progressive condition that causes you to lose control of your muscles in stages. Cerebrolysin is a drug that supports the nerves and may therefore have a beneficial effect in the treatment of ALS. This study assessed whether patients have a greater therapeutic benefit in treating the symptoms of ALS when Cerebrolysin is added to the standard treatment (riluzole).

Who can participate?
Patients aged 18 years and over with a confirmed diagnosis of ALS and a considerable increase in muscle tone

What does the study involve?
Patients received intravenous injections of 10 ml Cerebrolysin once a day, 5 days a week for the first month, then 3 days a week for the next 2 months, administered at home by a specialist nurse. Patients in the placebo group received the same treatment with 10 ml of normal saline. All patients received 50 mg of riluzole by mouth twice daily. Clinical assessments of motor and functional deterioration, spasticity and depressive symptoms were made before the start of treatment, at month 1, month 2 and at the end of the treatment period at month 3.

What are the possible benefits and risks of participating?
The potential benefit was an improvement in ALS symptoms, and no safety issues were expected.

Where is the study run from?
Instituto Cardiológico Banfield (ICB) (Argentina)

When is the study starting and how long is it expected to run for?
July 2020 to June 2022

Who is funding the study?
Instituto Cardiológico Banfield (ICB) (Argentina) and the study drug was provided by EVER Neuro Pharma GmbH

Who is the main contact?
Dr Afredo José Firstenfeld, alfredo.firstenfeld@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Add-on treatment with Cerebrolysin improves clinical symptoms in amyotrophic lateral sclerosis patients: results of a prospective, single-center, placebo-controlled, randomized, double-blind, Phase II study

Study objectives
Patients with amyotrophic lateral sclerosis (ALS) benefit more from treatment with a combination of Cerebrolysin and riluzole than they do from treatment with riluzole alone.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 12/01/2021, Comité De Ética De Clínica Privada Banfield Bancei (Félix de Azara 1780 – Banfield, Pcia de Bs. As, Buenos Aires, Banfield, Austria; +54 (0)11 3754-0050; info@clinicabanfield.com), ref: Carta de dictamen - Cerebrolysin - 12ene21

Study design
Investigator-initiated interventional prospective single-center placebo-controlled randomized double-blind Phase II study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Amyotrophic lateral sclerosis

Interventions
Patients were randomized 1:1 to Cerebrolysin or placebo (0.9% NaCl). An Excel-generated randomization list was used with blocks of 10 patients to account for balancing the sample size.

Patients received intravenous injections of 10 ml Cerebrolysin once a day, 5 days a week for the first month, then 3 days a week for the next 2 months, administered at home by a specialist nurse.

Patients in the placebo group received the same treatment with 10 ml of normal saline.

All patients received 50 mg of riluzole by mouth twice daily.

Clinical assessments of motor and functional deterioration, spasticity and depressive symptoms were made before the start of treatment, at month 1, month 2 and at the end of the treatment period at month 3.

Intervention Type
Drug

Pharmaceutical study type(s)
Clinical efficacy and safety study

Phase

Phase II

Drug/device/biological/vaccine name(s)
Cerebrolysin, riluzole

Primary outcome measure
Functional impairment is measured using the Amyotrophic Lateral Sclerosis Functional Rating Scale – revised (ALSFRS-R) at baseline and month 1

Secondary outcome measures
1. Functional impairment is measured using the Amyotrophic Lateral Sclerosis Functional Rating Scale – revised (ALSFRS-R) at baseline to months 2 and 3
2. Depressive symptoms are measured using the Beck's Depression Inventory-II (BDI-II) at baseline to months 1, 2, and 3
3. Spasticity is measured by the Modified Ashworth Scale (MAS) at baseline to months 1, 2, and 3
4. Gross motor skills are measured by the time taken to walk four meters, the walked distance in 120 seconds, and the number of knee bends to the opposite arm at baseline to months 1, 2, and 3
5. Hand strength is measured by an handheld dynamometer at baseline to months 1, 2, and 3

Overall study start date
08/07/2020

Completion date
02/06/2022

Eligibility

Key inclusion criteria
1. Either sex and at least 18 years of age
2. Clinically definite diagnosis of ALS according to the El Escorial and revised Airlie House diagnostic criteria
3. Limb onset and/or bulbar onset with pyramidal signs
4. Modified Ashworth Spasticity Scale score of 3
5. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Co-morbidities such as hepatic disease, renal failure or severe renal impairment, coronary disease, epilepsy, Parkinson’s disease, or dementia
2. Any condition that might interfere with compliance with study procedures or influence outcome assessment
3. Pregnant or breastfeeding
4. Participation in another interventional study within the previous 2 months
5. Contraindication to Cerebrolysin
6. Concomitant use of ginkgo biloba, erythropoietin, citicoline, and amantadine

Date of first enrolment
29/07/2021

Date of final enrolment
10/03/2022

Locations

Countries of recruitment
Argentina

Study participating centre
Instituto Cardiológico Banfield
Maipú 660
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Sponsor information

Organisation
Instituto Cardiológico Banfield

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Sponsor type

Hospital/treatment centre

Website
http://www.institutocardiologicobanfield.com/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto Cardiológico Banfield

Results and Publications

Publication and dissemination plan
The publication is in the submission process.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date