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Evaluation of efficacy and safety of Cerebrolysin as add-on therapy in patients with acute stroke after failed recanalisation therapy

Submission date
04/05/2020

Recruitment status
No longer recruiting

Registration date
25/05/2020

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke is a sudden interruption in the brain's blood supply. Early recanalization (restoring blood supply), brain protection and neurorecovery are the main goals of acute stroke treatment. Growing evidence suggests the beneficial effects of the medicine Cerebrolysin in acute stroke due to its neuroprotective actions (preventing brain cell death). Moreover the influence of Cerebrolysin on blood-brain barrier permeability has been speculated. The aim of this study is to assess the effectiveness and safety of Cerebrolysin in the early recovery phase in acute ischemic stroke after failed recanalization.

Who can participate?
Acute moderate and severe stroke patients, aged 18 or older, after failed recanalization

What does the study involve?
The study involves standard acute stroke assessment, recanalization and post procedural therapy and rehabilitation. For a minimum of 14 and maximum of 21 days patients in the investigational group receive Cerebrolysin as add-on treatment. The control group are 20 matched patients who did not sign the consent for Cerebrolysin treatment but signed the consent to take part in the study as controls. Outcomes are compared in both groups. The follow-up procedure includes routine brain CT or MRI scans (24 hours, 7 days and 6-12 months after symptom onset), and early and late clinical assessment.

What are the possible benefits and risks of participating?
Possible benefit for the participants is better clinical outcome after failed recanalization, regular follow-up by a dedicated stroke neurologist, and contribution to improved knowledge of the best stroke treatment. As the given drug has an excellent safety profile (according to known studies) there are no expected special risks for participants.

Where is the study run from?
University Hospital Centre Zagreb (Croatia)

When is the study starting and how long is it expected to run for?
August 2017 to January 2020

Who is funding the study?
University Hospital Centre Zagreb (Croatia)

Who is the main contact?
Prof. Zdravka Poljakovic
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EP - 43/17

Study information

Scientific Title
Efficacy of Cerebrolysin treatment as an add-on therapy to thrombolysis and thrombectomy in severe stroke patients with unsuccessful reperfusion - a prospective single-center clinical study

Acronym
CEREC-Stroke

Study objectives
Cerebrolysin therapy in patients with acute severe stroke after failed reperfusion therapy improves outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved in 02/11/2017, Ethics Committee of University Hospital Zagreb (Etičko Povjerenstvo KBC Zagreb, prof dr sc Darko Marčinko, Klinika za psihijatriju - President, Kišpatićeva 12, 10000 Zagreb, Croatia; no tel; jadranka.gregoran@kbc-zagreb.hr), ref: EP 43/17

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Acute ischemic stroke

Interventions
The study group are 20 patients with acute moderate and severe ischemic stroke, treated in University Hospital Centre Zagreb with either thrombolytic therapy alone, or thrombolysis and thrombectomy, who either proven by neuroimaging methods (MRI, MRA, DSA) or clinically (no change in NIHSS in the first 12 hours after recanalisation procedure) fulfil the criteria of unsuccessful reperfusion. Those patients will receive Cerebrolysin (30 ml i.v./day) starting the therapy the latest 24 hours after symptoms onset for a minimum of 14 and a maximum of 21 days. Efficacy will be assessed by NIH Stroke Scale/Score (NIHSS) at 7 and 14 days and early modified Rankin Scale (mRS) (by discharge) and mRS after 90 days and 1 year. Neuroimaging (brain CT or MRI) will be performed 24 hours after recanalisation therapy, on day 7 and a control imaging between 6 and 12 months of follow up. Signs of haemorrhagic transition will be analysed. All other therapeutic measures, as well as rehabilitation, will be according to the standard procedure. The control group are 20 matched patients who did not sign the consent for Cerebrolysin therapy but signed the consent to take part in the study as controls. Outcome measures are compared in both groups.

Intervention Type

Drug

Phase
Not Applicable

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

Primary outcome measure
Clinical outcome measured by modified Rankin Scale (mRS) after 12 months

Secondary outcome measures
1. Percentage of patients with haemorrhagic transformation assessed by control neuroimaging (brain CT and/or MRI) in 24 hours and 7 days interval since symptom onset
2. Mortality rate assessed by modified Rankin Scale (mRS) at any point during study follow-up (12 months)
3. Adverse events assessed by routine laboratory or clinical changes during treatment period with Cerebrolysin

Overall study start date
01/08/2017

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Aged 18 and over
2. Patients with acute ischemic stroke and initial NIHSS 8 or more
3. Treated in University Hospital Centre Zagreb with either thrombolytic therapy alone, or thrombolysis and thrombectomy, either proven by neuroimaging methods (MRI, MRA, DSA) or clinically (no change in NIHSS in the first 12 hours after recanalisation procedure) to fulfil the criteria of unsuccessful reperfusion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
46

Key exclusion criteria
1. Haemorrhagic transition of a stroke on control CT scan after reperfusion therapy
2. Patients taking MAO inhibitors
3. Patients known to be allergic to the drug
4. Patients taking part in another trial

Date of first enrolment
01/01/2018

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
Croatia

Study participating centre
University Hospital Centre Zagreb
Dept. of Neurology
Kispaticeva 12
Zagreb
Croatia
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Sponsor information

Organisation
University Hospital Centre Zagreb

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Sponsor type
Hospital/treatment centre

Website
https://www.kbc-zagreb.hr/

ROR
https://ror.org/00r9vb833

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Centre Zagreb

Results and Publications

Publication and dissemination plan
1. Case report - already published 2020
2. Poster with preliminary results - shown at ESOC 2019
3. Results of the study - July/August 2020 (planned)
4. Results of the study - ESOC November 2020

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2021	16/08/2021	Yes	No
Abstract results		01/09/2021	14/06/2023	No	No