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Using a neuroprotective drug to treat patients who have a serious type of brain bleeding caused by a rupture of a weakened blood vessel (aneurysm)

Submission date
28/06/2023

Recruitment status
No longer recruiting

Registration date
10/07/2023

Overall study status
Completed

Last Edited
07/07/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Aneurysmal subarachnoid hemorrhage (aSAH) is a very dangerous condition that can be life-threatening, even with prompt and intensive treatment. Around 15% of patients don't survive long enough to reach the hospital, and about 30% still die despite receiving the right treatment. For patients who have a more severe initial condition (measured using the Hunt Hess scale), this percentage can rise to 80%. Using neuroprotective drugs as an additional form of treatment has shown potential for improving the outcome in these cases.

Who can participate?
Adult patients with aneurysmal SAH and Hunt Hess grade 3 or more.

What does the study involve?
In addition to the standard treatment and monitoring, the study includes the use of a neuroprotective drug called Cerebrolysine as an additional therapy. The dosage prescribed is 30 ml per day for a duration of 10 days.

What are the possible benefits and risks of participating?
The potential benefit of this therapy is its neuroprotective effect, which can help reduce neuroinflammation and decrease the presence of harmful free radicals in the brain. The desired outcome is an improvement in functional recovery that exceeds expectations for this group of high-risk patients. As of now, there are no known risks associated with this therapy.

Where is the study run from?
University Hospital Zagreb, Department of Neurology (Croatia)

When is the study starting and how long is it expected to run for?
March 2021 to January 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Dr Zdravka Poljakovic, zdravka.po@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Cerebrolysin as add-on therapy in patients with high Hunt-Hess grade subarachnoidal hemorrhage

Acronym
CERESAH

Study objectives
Hypothesis:
Cerebrolysin as an add-on drug improves the 90-day functional outcome in patients with subarachnoidal haemorrhage and initial Hunt-Hess grade III and higher.

Aim of the study:
To investigate the efficacy and safety of Cerebrolysin as an add-on therapy in patients with HH grade III and higher.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/06/2021, Ethics committee of University Hospital Zagreb (Kispaticeva 12, Zagreb, 10000, Croatia; +385-1-2388888; kbc-zagreb@kbc-zagreb.hr), ref: 8.1.-21/142-1

Study design
Single center observational longitudinal case-control study during a 90 day follow-up period

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neuroprotection in patients with severe aneurysmal subarachnoidal haemorhage after endovascular treatment of ruptured aneurysm

Interventions
Patients with aneurysmal SAH and initial Hunt-Hess grade of 3 and more and secured aneurysm by endovascular approach will be included in the study and routinely treated during hospital stay. All patients will receive approved neuroprotective agent, Cerebrolysine (30 ml/day during 10 days) together with routine care. The diagnostic follow-up will be performed according to the routine protocol, and will include standard hemodynamic monitoring, TCD monitoring, ICP monitoring if required, EVD if required, intraventricular thrombolysis if required and routine neuroimaging. Patients will be then evaluated for their functional status 90 days after the bleeding. Functional outcome will be compared with literature data for the same group of patients with severe subarachnoidal bleeding.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
Functional outcome of the patients measured with mRS 90 days after the bleeding

Key secondary outcome(s))
1. Development of delayed neurological deficit during 21 days after the bleeding, verified by neuroimaging
2. Developement of the vasospasms during 14 days after the bleeding during TCD monitoring

3. Mortality after 90 days measured using patient records
4. Safety of Cerebrolysine (adverse events) up to end of study

Completion date
01/01/2025

Eligibility

Key inclusion criteria
1. Aneurysmal subarachnoidal haemorrhage
2. Inital Hunt-Hess grade 3 or higher
3. Endovasculary secured aneurysm
4. Availability to add-on treatment not more than 24 hours after embolisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Known allergy to Cerebrolysine
2. Refusal of participation in the study

Date of first enrolment
01/09/2021

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
Croatia

Study participating centre

University Hospital Zagreb, Department of Neurology
Kispaticeva 12
Zagreb
Croatia
10000

Sponsor information

Organisation
University Hospital Centre Zagreb

ROR
https://ror.org/00r9vb833

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request form to Zdravka Poljakovic, zdravka.po@gmail.com
The data which can be available are:
demographic data (blinded)
clinical data about the initial HH grade
clinical data about the aSAH treatment
Neuroimaging
TCD monitoring
safety data
early mRS -by discharge from the hospital
final mRS - 90 days after the initial bleeding
mortality data
relevant diagnostic work-up data if applicable (ICP, TCD, EVD; ivthrombolysis, etc)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Croatian		07/07/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			07/07/2023	No	No