

# A registry study to observe clinical practices, safety and effectiveness of routine use of Cerebrolysin in the treatment of patients with moderate to severe neurological deficits after acute ischaemic stroke

<b>Submission date</b> 06/04/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/09/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Stroke is a devastating disease and one of the primary causes for death and long-term morbidity imposing a heavy burden on patients, relatives and the health care system. Except for fibrinolytic therapy, which is only possible in a minor fraction of patients, there is no widely approved medication for the treatment of acute stroke.

Cerebrolysin has been approved for the treatment of stroke in over 45 countries worldwide. Since the approval of Cerebrolysin, stroke therapy has evolved, namely, with improved overall care, stroke units, more targeted rehabilitation, and the increasing availability of fibrinolytic therapy (rtPA, Actilyse) in specialized centers throughout the world. More recently, interventional therapies with various thrombus retrievers have emerged.

In addition, the Cerebrolysin treatment in stroke has evolved with different time windows, dosages and lengths of therapy being given in a pragmatic way by physicians within the specification of Product Characteristics for Cerebrolysin (SPC).

The main aim of this study is to systematically record Cerebrolysin treatment modalities and concomitant medication, according to local standards, in patients with moderate to severe neurological deficits after acute ischemic stroke and to assess the impact of these parameters on therapy outcome during early rehabilitation (day 21) and on day 90.

Besides this, the effectiveness and safety of Cerebrolysin therapy are monitored against the background of the now established and evolving stroke therapies (rtPA, thrombectomy). Furthermore, the effectiveness and safety of Cerebrolysin will be evaluated according to pre-existing diseases, concomitant medication and to applied rehabilitative actions. In the concomitant control group, these therapies alone or in combination will be compared to the addition of Cerebrolysin in these patients. Of interest is also the treatment in stroke units, with rtPA and systematic rehabilitation until day 21 and day 90.

An open observational treatment design has been chosen to collect data to capture the therapies as applied in real clinical practice. The pre-specified strategy follows the recommendations of the Principles for Good Research on Comparative Effectiveness (GRACE). A two-stage procedure is planned (Stage I: about 670 patients, Stage II: about 1400 patients).

**Who can participate?**

Patients aged 18 years or older, with clinical diagnosis of acute ischemic stroke, confirmed by imaging, no prior stroke, no prior disability.

**What does the study involve?**

All patients receive acute stroke care according to local treatment standards, which will not be amended or influenced by the study in any way. To evaluate the safety and effectiveness of Cerebrolysin in routine practice the outcome of Cerebrolysin-treated patients are compared with control group patients, who do not receive Cerebrolysin.

**What are the possible benefits and risks of participating?**

As this is a non-interventional study there are no additional treatments or evaluations. All patients receive acute stroke care according to local treatment standards, which will not be amended or influenced by the study. Patients are invited for two follow-up visits (day 21 and day 90) to evaluate and discuss the current status or their well-being. It is possible that a patient will receive Cerebrolysin according to treating physician's choice. Cerebrolysin might help to limit neurological deficits after stroke and enhance recovery.

The information obtained from this study will be helpful for the optimization and further research in the treatment of patients suffering from stroke.

There is no potential risk by participation in the study, the routine treatment will not be changed in any way.

**Where is the study run from?**

EVER Neuro Pharma (Austria)

**When is the study starting and how long is it expected to run for?**

February 2017 to May 2024

**Who is funding the study?**

EVER Neuro Pharma (Austria)

**Who is the main contact?**

Dr Marion Jech, [marion.jech@everpharma.com](mailto:marion.jech@everpharma.com)

## Contact information

**Type(s)**

Public

**Contact name**

Dr Marion Jech

**Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

NCT03480698

### **Secondary identifying numbers**

EVER-AT-0717

## **Study information**

### **Scientific Title**

Cerebrolysin REGistry Study in Stroke- a High-quality Observational Study of Comparative Effectiveness

### **Acronym**

C-REGS2

### **Study objectives**

This study investigates the clinical practices, safety and effectiveness of Cerebrolysin in routine treatment of patients with moderate to severe neurological deficits after acute ischemic stroke. The study takes place because real-world data for the use of Cerebrolysin is needed.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 23/01/2018, Ethikkommission des Landes Oberösterreich (Ethics Committee of Upper Austria, Wagner Jauregg Weg15 , Linz, 4021, Austria; +42 (0)5 768087 Ext: 28631; ethikkommission.ooe@kepleruniklinikum.at), ref: 1026/2017

### **Study design**

Prospective non-interventional registry study

### **Primary study design**

Observational

### **Secondary study design**

Registry study

### **Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Acute stroke

**Interventions**

Standard stroke care is compared to standard stroke care and Cerebrolysin as add-on.

All patients receive acute stroke care according to local treatment standards, which will not be amended or influenced by the study in any way. To evaluate the safety and effectiveness of Cerebrolysin in routine practice the outcome of Cerebrolysin-treated patients are compared with control group patients, who do not receive Cerebrolysin.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Cerebrolysin

**Primary outcome measure**

Neurologic disability measured using the modified Rankin Scale (mRS) at 3 months after stroke onset

**Secondary outcome measures**

1. Stroke severity measured using NIH Stroke Scale (NIHSS) at 21 days and 3 months after stroke onset
2. Neurologic disability measured using modified Rankin Scale (mRS) at 21 days after stroke onset
3. Cognitive impairment measured using Montreal - Cognitive Assessment (MoCA) at 3 months after stroke

**Overall study start date**

01/02/2017

**Completion date**

15/05/2024

**Eligibility****Key inclusion criteria**

1. Signed informed consent
2. Clinical diagnosis of acute ischemic stroke confirmed by imaging

3. Moderate to severe neurological deficits with NIH Stroke Scale (NIHSS) 8 to 15, both inclusive
4. No prior stroke
5. No prior disability
6. Patient's independence prior to stroke onset (pre-morbid mRS of 0 or 1)
7. Reasonable expectation of successful follow-up (max. 100 days)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

2,000

**Total final enrolment**

1851

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

25/04/2018

**Date of final enrolment**

31/12/2023

**Locations****Countries of recruitment**

Austria

Korea, South

Mexico

Philippines

Poland

Romania

Russian Federation

Ukraine

Viet Nam

**Study participating centre**

**Kepler University Hospital Linz (KUK)**

Klinik für Neurologie 2, Med Campus III, Kepler Universitätsklinikum  
Krankenhausstraße 9  
Linz  
Austria  
4020

**Study participating centre**

**University Hospital Tulln**

Abteilung für Neurologie  
Alter Ziegelweg 10  
Tulln  
Austria  
3430

**Study participating centre**

**Hospital Amstetten**

Abteilung für Neurologie  
Krankenhausstraße 21  
Amstetten  
Austria  
3300

**Study participating centre**

**University Hospital Innsbruck**

Universitätsklinik für Neurologie  
Anichstraße 35  
Innsbruck  
Austria  
6020

**Study participating centre**

**University Hospital Salzburg**

Christian-Doppler-Klinik  
Ignaz-Harrer-Straße 79  
Salzburg  
Austria  
5020

**Study participating centre**  
**Chungnam National University Sejong Hospital**  
20 Bodeum 7-ro  
Sejong  
Korea, South  
30099

**Study participating centre**  
**Daegu Catholic University Medical Center**  
33, Duryugongwon-ro 17-gil, Nam-gu  
Daegu  
Korea, South  
42472

**Study participating centre**  
**Southern Medical Hospital**  
Calle de Puente de Piedra No. 150  
Toriello Guerra  
Tlalpan  
Ciudad de Mexico  
Mexico  
14140

**Study participating centre**  
**Spitalul Clinic Judetean de Urgenta „Pius Brînzeu” Timisoara**  
Bulevardul Liviu Rebreanu 156  
Timișoara  
Romania  
300723

**Study participating centre**  
**Central District Hospital of Mozhaik**  
Mozhaik  
Russian Federation  
143200

**Study participating centre**  
**Region Clinical Hospital of Stavropol**  
Stavropol  
Russian Federation  
355029

**Study participating centre**  
**Kyiv Regional Clinical Hospital Stroke Unit**  
Kyiv  
Ukraine  
04107

**Study participating centre**  
**Vinnytsia Regional Psycho-Neurological Hospital**  
Vinnytsia  
Ukraine  
21037

**Study participating centre**  
**Thái Nguyên National Hospital**  
479 Lương Ngc Quyn, Phan Đình Phùng, Thành ph  
Thái Nguyên  
Viet Nam  
unkn.

**Study participating centre**  
**107 Szpital Wojskowy z Przychodnią Samodzielny Publiczny Zakład Opieki Zdrowotnej**  
ul. Kołobrzeska 44  
Wałcz  
Poland  
78-600

**Study participating centre**  
**Instytut Psychiatrii i Neurologii w Warszawie**  
ul. Jana Sobieskiego 9  
Warszawa  
Poland  
02-957

**Study participating centre**  
**Perpetual Succour Hospital, Cebu City**  
Rm 412 Perpetual Succor Hospital SPC Medical Specialty Center, Gorodo Avenue



Cebu City  
Philippines  
6000

**Study participating centre**  
**St. Luke's Medical Center - Quezon City**  
279 E. Rodriguez Sr. Blvd.  
Quezon City  
Philippines  
1112

## Sponsor information

**Organisation**  
EVER Neuro Pharma (Austria)

**Sponsor details**  
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4866  
+43 (0)7665205550  
office@everpharma.com

**Sponsor type**  
Industry

**Website**  
<http://www.everpharma.com/>

**ROR**  
<https://ror.org/032900178>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
EVER Neuro Pharma

**Alternative Name(s)**

EVER Pharma, EVER Neuro Pharma GmbH

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Austria

**Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

30/06/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Name and email: Marion Jech marion.jech@everpharma.com

Type of data: hardlocked patient level analysis data

When and how long available: at time of publication, for 5 years

Access: password protected link

Shared with whom: academic or governmental institutions

For what type of analyses: re-analysis based on preplanned SAP methodology

Consent of participants obtained: Any patient identifiers as well as country- and site-specific information will be removed for full data anonymisation

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version v3.3	01/03/2021	04/05/2021	No	No
<a href="#">Statistical Analysis Plan</a>	version v1	24/10/2017	04/05/2021	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.1	22/07/2024	12/09/2024	No	No