

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy of Intraventricular injection Actilyse(rt-PA) on recovery of patients with Spontaneous Intraventricular Hemorrhage (IVH)

Protocol summary

Study aim

Evaluation of the efficacy of Intraventricular injection Actilyse(rt-PA) on recovery of patients with Spontaneous Intraventricular Hemorrhage (IVH)

Design

In this double-blind clinical trial study (physician and patient), 40 patients with spontaneous IVH will be randomly divided into two separate groups by designing a parallel trial by considering the high inclusion and exclusion criteria and hospitalization in the neurosurgery ward of Poursina Hospital in Rasht. To block randomization, sealed envelope software will be used, considering 6 blocks based on gender. Allocation ratio equal to one and the study groups will include 20 patients receiving placebo and 20 patients receiving rt-PA Actylase.

Settings and conduct

Forty patients with spontaneous IVH admitted to Poursina Hospital in Rasht will be randomly divided into two separate groups. The groups will include 20 patients receiving placebo and 20 patients receiving rt-PA Actylase. In the group receiving the drug for the patient 2 mg in 2 ml rt-PA every 12 hours and in the placebo group 2 ml normal saline every 12 hours It will be injected into the ventricular space via external ventricular drainage(EVD) . During the days of drug injection, CT scans of the brain are performed daily to monitor asymptomatic bleeding and measure clot status. The medication is continued every 12 hours for up to 4 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients with diagnosis of spontaneous IVH Patients with diagnosis of spontaneous IVH and deep ICH with a volume of less than 20 cc No entry criteria All contraindications to the use of anticoagulants.....

Intervention groups

The groups will include 20 patients receiving placebo and

20 patients receiving rt-PA Actylase.

Main outcome variables

Glasgow Coma Scale, Glasgow Outcome Scale, spread of cerebral hematoma, bleeding, hydrocephalus, ventriculitis and brain infection .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200729048251N1**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

Registrant information

Name

babak alijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 1529

Email address

enayatbijani4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Intraventricular injection Actilyse(rt-PA) on recovery of patients with Spontaneous Intraventricular Hemorrhage (IVH)

Public title

Evaluation of the efficacy of Intraventricular injection Actilyse(rt-PA) on recovery of patients with Spontaneous Intraventricular Hemorrhage (IVH)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with diagnosis of spontaneous IVH Patients with diagnosis of spontaneous IVH and deep ICH with a volume of less than 20 cc

Exclusion criteria:

All contraindications to the use of anticoagulants Patients with known bleeding disorder Patients with evidence of uncontrolled hypertension Systolic pressure greater than 180 or diastolic pressure greater than 110 Patients with evidence of acute pancreatitis Patients with proven gastrointestinal ulcer disease in the last 3 months, esophageal varices, arterial aneurysms, venous arterial malformations Recent severe and dangerous bleeding Bacterial endocarditis and pericarditis Neoplasms with an increased risk of bleeding Severe liver disease such as liver failure, liver cirrhosis, increased portal vein pressure (esophageal varices) and active hepatitis Major surgery or significant trauma in the last 3 months Platelet count below 100,000 Recent extracorporeal trauma massage (less than 10 days), recent delivery, recent non-compressible vascular puncture such as subclavian or jugular vein

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

To block randomization, sealed envelope software will be used, considering 6 blocks based on gender. Allocation ratio equal to one and the study groups will include 20 patients receiving placebo and 20 patients receiving rt-PA octylase. Consent is obtained from both groups to participate in this study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind clinical trial study (physician and patient), 40 patients with spontaneous IVH who are randomly assigned to the neurosurgery ward of Poursina Hospital in Rasht will be randomly divided into two separate groups with Parallel trial design. Written consent has been obtained from the patient or the patient's companion to participate in the study, but no information has been given about which group to attend. Similarly, the treating physician is aware of the patient's presence but is not aware of which group to attend, and only the researcher and the person responsible for assessing the outcome are aware of the details of the drug vial or placebo injection for the patient.

Placebo

Used

Assignment

Parallel

Other design features

This study was designed considering the high mortality rate of patients with spontaneous IVH and the importance of improving these patients and the positive results of similar studies.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Guilan University of Medical Sciences

Street address

Rasht - Namjoo St. - Shahid Siadati St. - Opposite to 17 Shahrivar Hospital - Old Building of the Faculty of Health - Vice Chancellor for Research and Technology

City

Rasht

Province

Guilan

Postal code

.

Approval date

2020-07-15, 1399/04/25

Ethics committee reference number

IR.GUMS.REC.1399.191

Health conditions studied**1****Description of health condition studied**

Spontaneous Intraventricular Hemorrhage

ICD-10 code

I61.5

ICD-10 code description

Nontraumatic intracerebral hemorrhage, intraventricular

Primary outcomes

1

Description

Recovery of patients with determining GCS and GOS

Timepoint

During hospitalization up to four months after discharge

Method of measurement

with determining GCS and GOS

Secondary outcomes

1

Description

Death.

Timepoint

From hospitalization to four months after discharge

Method of measurement

During the treatment process, daily follow-up of patients in case of patient death at the time of hospitalization is recorded as a case of death, and in case of patient death within four months after discharge, information is obtained from the patient's family through telephone follow-up.

2

Description

Cerebral hematoma volume change.

Timepoint

At the time of hospitalization

Method of measurement

During the treatment process, daily follow-up of patients on the days of drug injection is performed daily CT scan of the brain to monitor asymptomatic bleeding and measure clot status. Medication is continued every 12 hours for up to 4 days. In case of severe complications (symptomatic bleeding), the drug should be stopped immediately.

3

Description

Brain infection.

Timepoint

At the time of hospitalization

Method of measurement

During the treatment process, daily follow-up of patients and sending csf samples via evd and examination of infection markers in CSF is performed.

4

Description

Bleeding

Timepoint

At the time of hospitalization

Method of measurement

During the treatment process, asymptomatic bleeding is monitored by daily follow-up of patients. In case of severe complications (symptomatic bleeding), the drug should be stopped immediately. Serum coagulation factors are monitored daily.

Intervention groups

1

Description

Intervention group: In this clinical trial study, 20 patients with spontaneous IVH who underwent external ventricular drainage (EVD) due to hydrocephalus symptoms and were admitted to the neurosurgery ward of Poursina Hospital in Rasht, taking into account the high inclusion and exclusion criteria. It is randomly assigned to the drug group and the patient will be injected with 2 mg in 2 ml rt-PA (octylase) every 12 hours via EVD. According to studies, the above drug dose is safe. During the days of drug injection, CT scans of the brain are performed daily to monitor asymptomatic bleeding and measure clot status. Medication is continued every 12 hours for up to 4 days. In case of severe complications (symptomatic bleeding), the drug should be stopped immediately. Serum coagulation factors and markers of infection are monitored daily in the CSF. Blood pressure, temperature are checked every 8 hours when receiving the drug.

Category

Treatment - Drugs

2

Description

Control group: 20 patients with spontaneous IVH who underwent external ventricular drainage (EVD) due to hydrocephalus symptoms and were admitted to the neurosurgery ward of Poursina Hospital in Rasht randomly in the placebo group due to high inclusion and exclusion criteria. And 2 ml of normal saline will be injected into the ventricular space every 12 hours to 4 days via EVD.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Enayat Bijani

Street address

Department of Neurosurgery, Poursina Hospital, Parstar St., Farhang Square, Rasht, Postal Code 13194-41937

City

Rasht

Province

Guilan
Postal code
41937-13194 کد پستی
Phone
+98 13 3333 1529
Fax
+98 13 3333 9842
Email
enayatbijani4@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammad Reza Naghipour
Street address
Rasht - Namjoo St. - Shahid Siadati St. - Opposite to
17 Shahrivar Hospital - Vice Chancellor for Research
and Technology
City
Rasht
Province
Guilan
Postal code
. .
Phone
+98 13 3333 5821
Fax
+98 13 3333 6395
Email
research@gums.ac.ir
Web page address
<https://ethics.research.ac.ir/PortalCommittee.php?code=IR.GUMS.REC>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences
Full name of responsible person
Enayat Bijani
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Department of Neurosurgery,Poursina Hospital,
Parstar St., Farhang Square, Rasht , Postal Code
13194-41937
City
rasht
Province
Guilan
Postal code
41937-13194 کد پستی
Phone
+98 13 3333 1529
Fax
+98 13 3333 9842
Email
enayatbijani4@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Enayat Bijani
Position
Neurosurgery Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Department of Neurosurgery,Poursina Hospital,
Parstar St., Farhang Square, Rasht , Postal Code
13194-41937
City
Rasht
Province
Guilan
Postal code
41937-13194 کد پستی
Phone
+98 13 3333 1529
Fax
+98 13 3333 9842
Email
Enayatbijani4@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person

Enayat Bijani

Position

Neurosurgery Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Department of Neurosurgery, Poursina Hospital,
Parstar St., Farhang Square, Rasht , Postal Code
13194-41937

City

Rasht

Province

Guilan

Postal code

41937-13194 کد پستی

Phone

+98 13 3333 1529

Fax

+98 13 3333 9842

Email

enayatbijani4@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available