Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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. Took. 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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Person responsible for updating data

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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