

CLEAR IVH: Clot Lysis: Evaluating Accelerated Resolution of Intraventricular Hemorrhage (IVH)

Submission date 16/07/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/04/2019	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00650858

Protocol serial number
8523-072004

Study information

Scientific Title
CLEAR IVH: Clot Lysis: Evaluating Accelerated Resolution of Intraventricular Hemorrhage (IVH)

Acronym

CLEAR IVH

Study objectives

The specific objective of this trial is to determine the lowest dose possible with the best pharmacokinetic and safety profile and its ability to remove blood clot from the ventricular system

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intraventricular hemorrhage

Interventions

Stage 1: patients received intraventricular injections of either 0.3 mg or 1.0 mg of rt-PA every 12 hours for up to eight doses

Stage 2: patients will receive 1.0 mg every 8, 6, or 4 hours depending on the dose tier open at the time of enrollment

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. 30-day mortality
2. Incidence of ventriculitis, meningitis
3. Rate of bleeding events

Key secondary outcome(s)

1. Rate of clot size reduction at Days 4-5 determined by CT scans (stages 1 and 2)
2. 90 & 180 day GOS, Rankin, Stroke Impact Scale (stage 2 only)

Completion date

30/04/2007

Eligibility

Key inclusion criteria

1. Age 18-75
2. Intraventricular catheter (IVC) placed as standard of care using less than or equal to two complete passes
3. Spontaneous intracerebral hemorrhage (ICH) <30 cc
4. Able to receive first dose within 48 hours of computed tomography (CT) scan diagnosing IVH (providing the time of symptom onset to diagnostic CT does not exceed 12 hours)
5. Clot size measured on CT scan done 6 hours after IVC placement must be equal to the presentation clot size + 5 cc (as determined by the $(A \times B \times C)/2$ method)
6. On stability CT scan either the 3rd or 4th ventricles are occluded with blood (no evidence of cerebrospinal fluid [CSF] flow on CT)
7. Systolic blood pressure (SBP) <200 mmHg sustained for 6 hours
8. Historical Rankin of 0 or 1

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

All

Key exclusion criteria

1. Suspected or untreated aneurysm or arterio venous malformation (AVM) (unless ruled out by angiogram or magnetic resonance angiography [MRA]/magnetic resonance imaging [MRI])
2. Clotting disorders
3. Patients with platelet count <100,000, international normalized ratio (INR) >1.7, prothrombin time (PT) >15 s, or an elevated activated partial thromboplastin time (APTT)
4. Pregnancy (positive pregnancy test)
5. Infratentorial hemorrhage (i.e. parenchymal/posterior fossa hematoma; all cerebellar hematomas are excluded)
6. Subarachnoid hemorrhage (SAH). (An angiogram should be obtained when the diagnostic CT scan demonstrates subarachnoid hemorrhage or any hematoma location or appearance not strongly associated with hypertension. If the angiogram does not demonstrate a bleeding source that accounts for the hemorrhage, the patient is eligible for the study.)
7. ICH enlargement during the 6-hour stabilization period (6 hours after IVC placement)
8. Internal bleeding, involving retroperitoneal sites, or the gastrointestinal, genitourinary, or

respiratory tracts

9. Superficial or surface bleeding, observed mainly at vascular puncture and access sites (e.g. venous cutdowns, arterial punctures) or site of recent surgical intervention

10. Known risk for embolization, including history of left heart thrombus, mitral stenosis with atrial fibrillation, acute pericarditis, and subacute bacterial endocarditis

11. Prior enrollment in the study

12. Any other condition that the investigator believes would pose a significant hazard to the subject if the investigational therapy were initiated

13. Participation in another simultaneous medical investigation or trial

Date of first enrolment

01/02/2004

Date of final enrolment

30/04/2007

Locations

Countries of recruitment

United States of America

Study participating centre

Johns Hopkins University

Baltimore, Maryland

United States of America

21287

Sponsor information

Organisation

Johns Hopkins University (USA)

ROR

<https://ror.org/00za53h95>

Funder(s)

Funder type

Industry

Funder Name

FDA Office of Orphan Products Development

Funder Name

Genentech

Alternative Name(s)

Genentech, Inc., Genentech USA, Inc., Genentech USA

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012	11/04/2019	Yes	No
Results article	results	01/06/2012	11/04/2019	Yes	No
Results article	results	01/06/2013	11/04/2019	Yes	No
Results article	results	01/09/2015	11/04/2019	Yes	No
Results article	results	01/03/2013	11/04/2019	Yes	No
Results article	results	01/12/2011	11/04/2019	Yes	No
Basic results				No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes