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

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

Plain English Summary

Not provided at time of registration

Study website

http://www.neuro.jhmi.edu/ivh

Contact information

Type(s)

Scientific

Contact name

Dr Daniel Hanley

Contact details

600 N. Wolfe Street Jefferson 1-109 Baltimore, Maryland United States of America 21287

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00650858

Secondary identifying numbers

8523-072004

Study information

Scientific Title

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

Acronym

CLEAR IVH

Study hypothesis

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Condition

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

Primary outcome measure

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

Secondary outcome measures

- 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)

Overall study start date

01/02/2004

Overall study end date

30/04/2007

Eligibility

Participant 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 x B x 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

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

Participant 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

Recruitment start date 01/02/2004

Recruitment end date 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)

Sponsor details

600 N. Wolfe Street Jefferson 1-109 Baltimore, Maryland United States of America 21287

Sponsor type

University/education

Website

http://www.neuro.jhmi.edu/ivh

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

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Basic results	Details	Date created	Date added	Peer reviewed? No	Patient-facing? No
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