ISRCTN47341677 https://doi.org/10.1186/ISRCTN47341677

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

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

Not Specified

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

Stage 1 complete (n = 16); Stage 2 open (n = 36-48)

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