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Evaluation of novel thrombolytic TGD001 in patients with acute ischemic stroke

Submission date
25/07/2026

Recruitment status
Recruiting

Registration date
28/09/2026

Overall study status
Ongoing

Last Edited
28/09/2026

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
An acute ischaemic stroke happens when a blood clot blocks blood flow to part of the brain. This can damage brain tissue and may cause long-term disability. Current treatments include medicines that dissolve blood clots and a procedure to remove the clot, called thrombectomy. However, these treatments do not always work well enough, so better treatments are needed. This study is testing a new clot-dissolving medicine called TGD001. TGD001 targets a part of blood clots called von Willebrand factor, which is different from the main target of currently used clot-dissolving medicines. The main aim of the study is to find out whether TGD001 is safe and well tolerated in people who have had an acute ischaemic stroke. The study will also look at how TGD001 affects blood flow in the brain and recovery after stroke.

Who can participate?
Adults aged 18 years or older who have had an acute ischaemic stroke confirmed by a brain scan may be able to take part. This includes some people who have had a thrombectomy and some people who are not suitable for standard clot treatments. Men and women can take part, but women who are pregnant or breastfeeding cannot participate.

What does the study involve?
About 130 people will take part at specialist stroke hospitals.
The study has two parts. In the first part, small groups of participants receive a single dose of TGD001 into a vein. Different doses are studied to help identify a suitable dose for further testing. In the second part, participants are randomly assigned to receive either TGD001 or a placebo treatment. Neither the participant nor most of the study team will know which treatment was given.
Participants will continue to receive the standard stroke care that is appropriate for them. During the study, doctors will monitor participants for side effects. Participants will also have blood tests, brain scans and assessments of their stroke symptoms and ability to carry out everyday activities. Each participant will be followed for about 90 days.

What are the possible benefits and risks of participating?
Participants may or may not benefit directly from taking part. TGD001 may help dissolve blood clots and improve blood flow to the brain, but it is not yet known whether it will improve

recovery from stroke. Participants will also be closely monitored during the study. The information collected may help researchers better understand TGD001 and may contribute to better treatments for people with stroke in the future.
The main potential risk of TGD001 is bleeding, which may occur in the brain or elsewhere in the body. There is also a possibility of an allergic or treatment-related reaction. Blood tests, brain scans and other study procedures may also cause discomfort or carry small risks. Participants will be monitored and treated if any problems occur.

Where is the study run from?
The study is managed by TargED Biopharmaceuticals B.V. in Utrecht, the Netherlands.

When is the study starting and how long is it expected to run for?
March 2026 to December 2027

Who is funding the study?
TargED Biopharmaceuticals B.V. (Netherlands)

Who is the main contact?
Sonja Visscher, clinops@targedbio.com

Contact information

Type(s)
Scientific, Public

Contact name
Dr Josefin-Beate Holz

Contact details
Princetonlaan 6
Utrecht
Netherlands
3584 CB
+31 (0)30 2028079 ext 00
regulatory@Targedbio.com

Type(s)
Scientific, Public

Contact name
Dr Sonja Visscher

Contact details
Princetonlaan 6
Utrecht
Netherlands
3584 CB
+31 (0)30 2028079 ext 00
clinops@targedbio.com

Type(s)

Principal investigator

Contact name
Dr Christine Roffe

Contact details
Guy Hilton Research Centre
1 Thornburrow Drive
Stoke-on-Trent
United Kingdom
ST4 7QB
+44 (0)1782 679484
Christine.Roffe@uhnm.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
1013913

Sponsor's protocol code number
TG1-CL-201

Study information

Scientific Title
A Phase Ib/IIa open-label dose-finding followed by randomized, double-blind, placebo-controlled expansion study to evaluate the safety, tolerability, and preliminary efficacy of TGD001 in patients with acute ischemic stroke

Acronym
TG1-CL-201

Study objectives
Primary objective:
To assess the safety and tolerability of single intravenous (IV) doses of TGD001 in participants with an acute ischemic stroke (AIS) diagnosis, supported by neuroimaging, who either receive endovascular thrombectomy (EVT) or do not receive EVT or standard of care (SOC) intravenous thrombolysis (IVT).

Secondary objectives:
1. To assess the rates of asymptomatic intracranial hemorrhage (aICH)
2. To determine the pharmacokinetic (PK) profile of single IV doses of TGD001 in participants with AIS
3. To assess recanalization post-intervention
4. To assess reperfusion post-intervention
5. To assess neurological outcome at 90 days post-intervention
6. To determine the functional status at 90 days post-intervention

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Safety

Study type(s)
Efficacy, Safety, Treatment, Other

Health condition(s) or problem(s) studied
Acute ischemic stroke

Interventions
The trial consists of two parts and includes prespecified groups of participants with acute ischemic stroke.

Phase 1b is an open-label, single-dose escalation and expansion phase. Participants receive one intravenous administration of TGD001. Dose-escalation and de-escalation decisions are overseen by the Data Safety Monitoring Committee (DMC), which will select the dose or doses for further evaluation. Three dose levels are planned for each patient group. Additional dose levels may be established by the DMC.

Phase 2a is a randomized, double-blind, placebo-controlled expansion phase. Participants receive one intravenous administration of either TGD001 or placebo. Randomisation occurs before treatment according to a prespecified randomisation schedule.

All participants are followed for approximately 90 days. Follow-up includes safety assessments, laboratory and pharmacokinetic/pharmacodynamic sampling, brain imaging, and neurological and functional outcome assessments.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
TGD001

Primary outcome(s)
1. Symptomatic intracranial haemorrhage (sICH) is assessed according to the Heidelberg Bleeding Classification during the post-intervention follow-up (90 days)
2. Treatment-emergent adverse events (TEAEs) are assessed by standard adverse-event monitoring throughout the study follow-up period up to Day 90

Key secondary outcome(s)
1. Asymptomatic intracranial haemorrhage (aICH) is assessed by brain imaging during post-intervention follow-up (90 days)
2. Pharmacokinetics of TGD001 are assessed from plasma TGD001 concentrations and derived pharmacokinetic parameters, including Cmax, Tmax, AUC and t½, using serial blood samples collected at baseline and up to six timepoints 72 hours after treatment
3. Recanalization is assessed using computed tomography angiography (CTA) or magnetic resonance angiography (MRA) during post-intervention follow-up (90 days)
4. Reperfusion/perfusion deficit is assessed using computed tomography perfusion (CTP) or magnetic resonance perfusion (MRP) during post-intervention follow-up (90 days)
5. Neurological outcome is assessed using the National Institutes of Health Stroke Scale (NIHSS) during post-intervention follow-up and at Day 90
6. Functional outcome is assessed using the modified Rankin Scale (mRS) during follow-up and at Day 90

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Informed consent obtained from the participant or a participant representative in accordance with local legal and institutional review board (IRB) and independent ethics committee (IEC) requirements
3. Functionally independent (Modified Rankin Scale [mRS] 0-2) prior to stroke onset
4. Diagnosis of AIS supported by neuroimaging:
4.1. A visible occlusion on computed tomography angiography (CTA) or magnetic resonance angiography (MRA) imaging; and/or
4.2. An ischemic lesion (Alberta stroke program early CT score [ASPECTS] 6 - 10) on non-contrast computed tomography (NCCT) or magnetic resonance imaging (MRI), with target mismatch on computed tomography perfusion (CTP) or magnetic resonance perfusion (MRP) imaging, if performed
5. National Institutes of Health Stroke Scale (NIHSS) ≥5 and that remains ≥5 immediately before enrollment
6. Participants who:
6.1. Meet the local endovascular thrombectomy (EVT) eligibility requirements and undergo EVT (Groups 1 and 2), or
6.2. Do not receive EVT or SOC IVT (Group 3)

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to undergo both MRI and CT imaging
2. Intracranial hemorrhage on pre-intervention imaging
3. Demarcated infarct or early ischemic changes resulting in ASPECTS ≤5 on pre-intervention imaging
4. Active internal bleeding
5. Known hereditary or acquired hemorrhagic diathesis, coagulation factor deficiency
6. Use of an anticoagulant, including but not limited to direct oral anticoagulants (DOACs) or warfarin, within the last 48 hours or recent oral anticoagulant therapy with international normalized ratio (INR) ≥1.7. If the DOAC level is measured and found to be below the therapeutic threshold (Factor Xa inhibitor levels of less than 50 ng/ml or anti-Xa levels of less than 0.5 IU/ml), the participant can be enrolled regardless of the recency of the last dose.
7. Use of any medication and/or recent procedure that is known to significantly increase the bleeding risk (at the discretion of the investigator)
8. More than four recanalization attempts of target lesion with stent retriever or aspiration device during EVT prior to the use of the trial intervention
9. Coma, and/or NIHSS >25
10. Seizure(s) at stroke onset if this precludes obtaining an accurate baseline NIHSS
11. Severe, uncontrolled hypertension (systolic blood pressure >180 mmHg or diastolic blood pressure >110 mmHg). NOTE: If the blood pressure can be successfully reduced and maintained at an acceptable level using European Stroke Organization (ESO) guidelines-recommended medication (including i.v. antihypertensive drips), the participant can be enrolled.
12. Platelet count <100.000/µl
13. Blood glucose <50 mg/dl (2.8 mmol/l) or >400 mg/dL (22.20 mmol/l)
14. Impaired renal function as indicated by estimated glomerular filtration rate (GFR) below 30 ml/min/1.73 m^2 or requiring hemodialysis/peritoneal dialysis
15. Severe liver fibrosis or portal hypertension
16. Female who is pregnant, lactating, or has a positive pregnancy test at the time of admission
17. Evidence of active systemic infection that could have led to presumed septic embolus, suspicion of bacterial endocarditis
18. Surgery or trauma affecting intracranial or intraspinal areas within the last 2 months
19. Pre-existing severe medical, neurological, or psychiatric disease that would significantly confound the neurological or functional evaluations (investigator judgment)
20. History of cerebrovascular incident in the last 3 months

21. Intracranial neoplasm, arteriovenous malformation, or aneurysm
22. Other serious, advanced, or terminal illness in the last 3 months (investigator judgment) or life expectancy is less than 6 months
23. Known hypersensitivity to any of the trial treatments or their excipients or to drugs of similar chemical classes
24. Participant participating in a trial involving an investigational drug or device that would impact this trial within the last 30 days

Date of first enrolment
11/03/2026

Date of final enrolment
06/12/2027

Locations

Countries of recruitment
United Kingdom

England

Belgium

France

Germany

Netherlands

Poland

Serbia

Spain

United States of America

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
Kings College Hospital
Denmark Hill

London
England
SE5 9RS

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
University Hospital Hamburg-Eppendorf
Martinistrasse 52
Hamburg
Germany
20246

Study participating centre
Klinikum Altenburg Land
Am Waldessaum 10
Altenburg
Germany
4600

Study participating centre
Universitätsklinikum Heidelberg
Im Neuenheimer Feld 400
Heidelberg
Germany
69120

Study participating centre
Klinikum Ernst von Bergmann
Charlottenstraße 72
Potsdam
Germany
14467

Study participating centre
Uniklinikum Dresden
Fetscherstraße 74
Dresden
Germany
1307

Study participating centre
Universitätsklinikum Bonn
Venusberg Campus 1
Bonn
Germany
53127

Study participating centre
Universitätsklinikum Tübingen
Hoppe-Seyler-Str. 3
Tübingen
Germany
72076

Study participating centre
Universitätsmedizin Charité
Hindenburgdamm 30a
Berlin
Germany
12203

Study participating centre
Hospital Universitario Virgen Macarena
Avenida Dr. Fedriani 3
Sevilla
Spain
41008

Study participating centre
Hospital Germans Trias i Pujol
Carretera de Canyet 8916, Badalona
Barcelona
Spain
Badalona

Study participating centre
Hospital Virgen de la Arrixaca
Caretta Madrid-Cartagena, El Palmar
Murcia
Spain
30120

Study participating centre
Hospital Álvaro Cunqueiro
Estrada de Clara Campoamor 341, Vigo
Pontevedra
Spain
36312

Study participating centre
Hospital Universitario Virgen del Rocío
Avenida Manuel Siurot
Sevilla
Spain
41013

Study participating centre
Hospital Universitari Vall d'Hebron
Pg. de la Vall d'Hebron, 119
Barcelona
Spain
8035

Study participating centre
Hospital Clínico Universitario de Valladolid
Avenida de Ramón y Cajal 3

Valladolid
Spain
47003

Study participating centre
Hospital Universitari de Girona
Avinguda de França
Girona
Spain
17007

Study participating centre
University Hospital in Krakow
Macieja Jakubowskiego 2
Krakow
Poland
30-688

Study participating centre
Górnoslaskie Centrum Medyczne im. Leszka
Gieca Slaskiego Uniwersytetu Medycznego w Katowicach ul. Ziołowa 45-47
Katowice
Poland
40-635

Study participating centre
Military Medical Academy
Crnotravska 17
Belgrade
Serbia
11000

Study participating centre
University Clinical Center Nis
dr Zoran Djindjic Boulevard 48
Nis
Serbia
18000

Study participating centre
University Clinical Center Kragujevac
Zmaj Jovina 30
Kragujevac
Serbia
34000

Study participating centre
University Clinical Centre of Vojvodina
Hajduk Veljkova 1
Novi Sad
Serbia
21137

Sponsor information

Organisation
TargED Biopharmaceuticals B.V.

Funder(s)

Funder type

Funder Name
TargED Biopharmaceuticals B.V.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date