

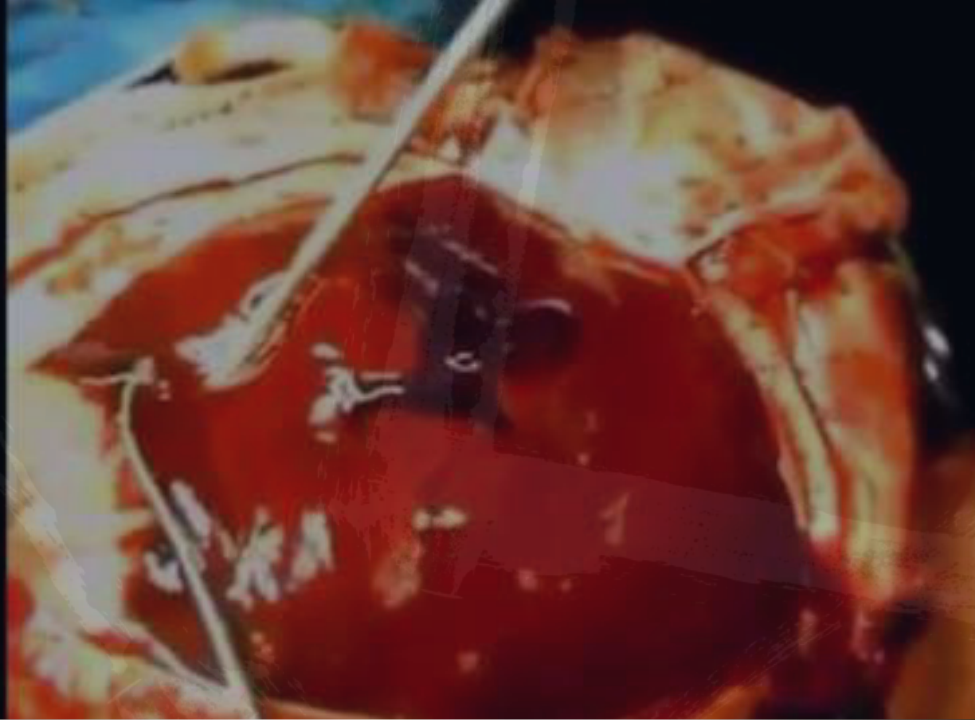
Update on ongoing clinical trials

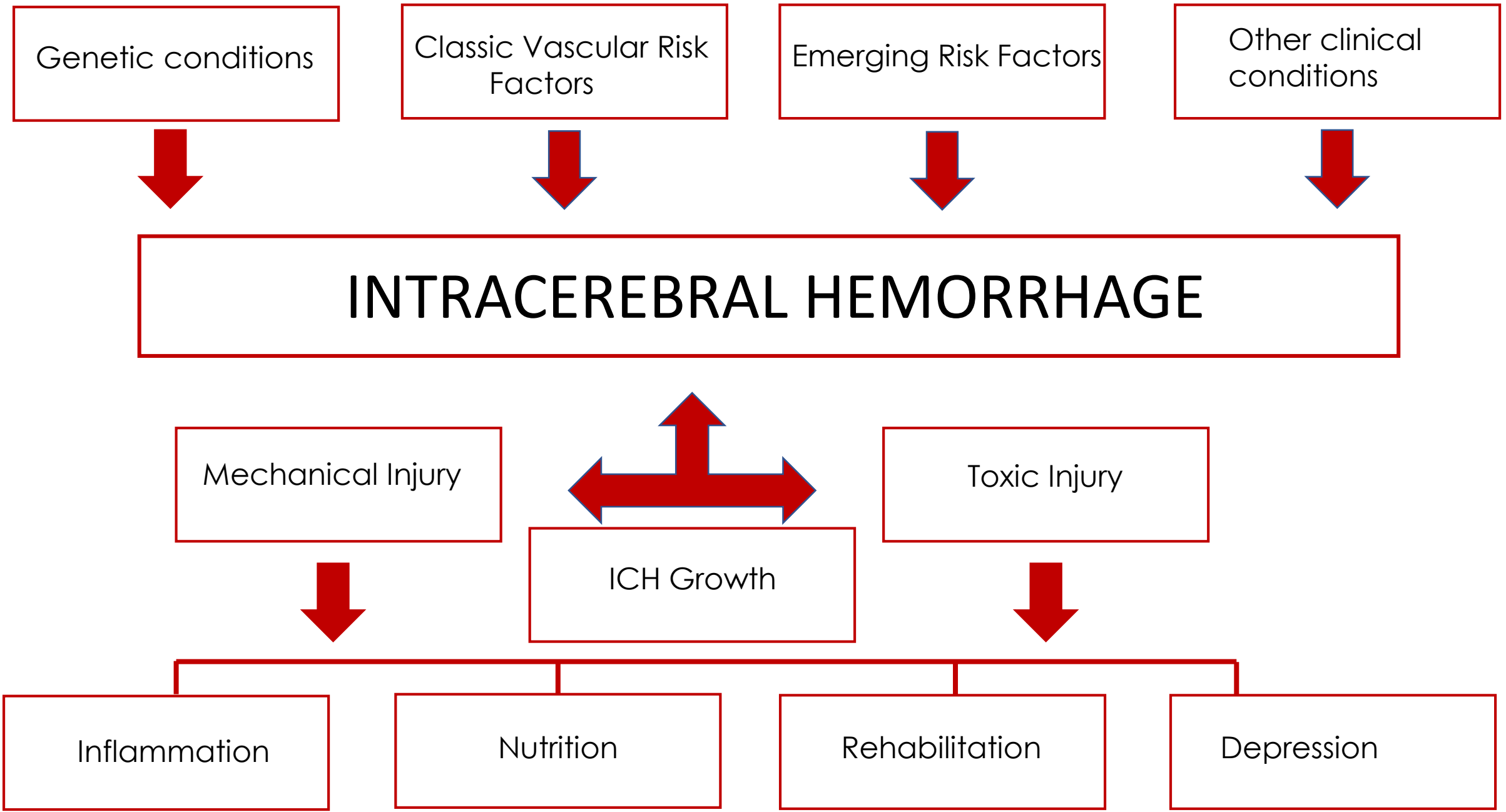
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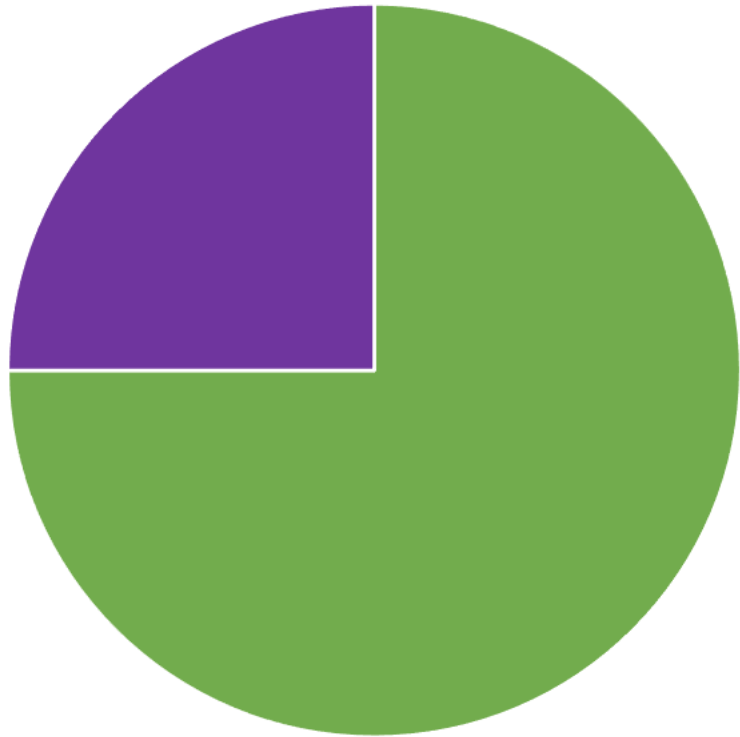
RICORS-ICTUS. III Stroke Congress.

NEW INSIGHTS AND PERSPECTIVES ON INTRACEREBRAL HEMORRHAGE: A COMPREHENSIVE UPDATE





Recruiting and not yet recruiting interventional clinical trials



Looking for participants

- Not yet recruiting (19)
- Recruiting (57)

Study Phase ⓘ

- Early Phase 1 (0)
- Phase 1 (7)
- Phase 2 (17)
- Phase 3 (10)
- Phase 4 (5)
- Not applicable (41)

Target: evacuation of the hematoma

Title	Start/Completion	Phase	Intervention	Primary Outcome
Early Minimally Invasive Image Guided Endoscopic Evacuation of Intracerebral Haemorrhage (EMINENT-ICH)	Start: 1/1/2024 Completion: 12/2029	Not Applicable (NA)	Early minimally invasive image-guided hematoma evacuation within 24 hours +BMT vs BMT	Good functional outcome, measured by the modified Rankin Scale (mRS) ≤ 3 points
DTI-guided Minimally Invasive Hematoma Evacuation for Intracerebral Hemorrhage (GLAMOR)	Start: 08/2023 Completion: 08/2027	NA	Minimally invasive hematoma evacuation PLUS best medical therapy vs BMT 20-40ml, midline < 3mm The degree of integrity and continuity of the corticospinal tract on the lesion side of DTI-MRI grade 2~4; <24 hours ; GCS score ≥ 4 points	Proportion of score of 0-3 on the mRankin scale at 180 days
Minimally Invasive Intracranial Hematoma Aspiration for Spontaneous Intracerebral Hemorrhage	Start: 07/2023 Completion: 06/2025	NA	Minimally invasive hematoma aspiration drainage combined with urokinase injection within 48 hours in Deep ICH of 20-40 ml vs drug-conserved group	mRS at 6 months
Dutch Intracerebral Hemorrhage Surgery Trial (DIST)	Start: 11/2022 Completion: 04/2027	NA	Minimally invasive endoscopy-guided surgery (Artemis Neuro Evacuation Device)+BMT in ICH > 10 ml and <8 hours	mRS at 180 days
Fingolimod in Minimal Invasive Treatment of Intracerebral Hemorrhage (FMII C)	Start: 10/2023 Completion: 12/2025	1-2	0.5mg/day oral fingolimod over a course of 3 consecutive days vs control group. All patients will receive minimal invasive puncture and drainage of hematoma. Deep ICH>20 ml < 24 hours GCS 5-12	mRS at 90 and 180 days

Target: evacuation of the hematoma

Title	Start/Completion	Phase	Intervention	Primary Outcome
Minimal Invasive Surgical Intracerebral Hemorrhage Removal (HEALME)	Start: 11/2024 Completion: 12/2025	Not applicable (NA)	MIS (Artemis) vs BMT ≤8 hours 20-80 ml NIHSS≥6 and Glasgow Coma Scale score 8-12 160mmHg target SBP	Feasibility mRS day 30 and 90 Mortality 7 and 30 days Quality of life (NIHSS and EQ-5D-5L)
Ultra-Early, Minimally Invasive IntraCerebral Haemorrhage evacuation Versus Standard treatment (EVACUATE)	Start: 11/2020 Completion: 12/2026	NA	MIS (Aurora surgiscope and evacuator) ≤8 hours vs standard care ≥20mL NIHSS≥6	mRS 0-3 at 6 months
Efficacy and Safety of NeuroEndoscopic Surgery for IntraCerebral Hemorrhage (NESICH)	Start: 11/2022 Completion: 09/2026	NA	Endoscopic surgery< 24 hours vs MM Deep ICH ≥ 25 ml. Blood pressure recorded 6 hours prior to randomization consistently controlled at 180 mmHg or less.	mRS 0-3 at 6 months Mortality at 6 months
Robotic Assisted Evacuation of Subacute and Chronic Supratentorial Deep Hypertensive Intracerebral Hemorrhage	Start: 09/2022 Completion: 06/2025	NA	Robotic Assisted Evacuation+MM vs MM and same rehabilitation therapy three times per week for 180 days at one facility ≥ 18 and ≤ 75 years Deep , 15-30 ml, < 24 hours stable hematoma (hematoma growth<5 mL) for at least 12 h after diagnostic CT GCS>8, NIH Stroke Scale (NIHSS)>5 mRS 3-5	mRS 0-2 at 6 months
Tract-based Artificial Intelligence (AI) Robot Guiding System in Basal Ganglion Hemorrhage Evacuation	Start: 1/2025 Completion: 12/2027	NA	MIS with Tract-based AI Robot Guiding System vs conservative group within 72 hours 18-70 years 15 to 30 mL, Deep, GCS ≥ 9 Hematoma stability shown by a CT scan at least 6 hours after the diagnostic CT (hematoma volume increase < 5 ml)	mRS≤3 at 6 months

Target: Hematoma expansion

Title	Start/Completion	Phase	Intervention	Primary Outcome
Recombinant Factor VIIa (rFVIIa) for Hemorrhagic Stroke Trial (FASTEST)	Start: 12/2021 Completion: 01/2028	3	Participants will be randomized in a double-blinded fashion to rFVIIa 80 µg/kg dose (maximum 10 mg dose) or placebo. Both arms plus BMT ICH vol 2-60 ml within 120 minutes	mRS at 180 days
Tranexamic acid for hyperacute primary intracerebral haemorrhage (TICH-3)	Start: 05/2021 Completion: 02/2028	3	Intravenous tranexamic acid 2g: 1g loading dose given as 100 mls infusion over 10 minutes, followed by 1g in 250 mls infused over 8 hours vs placebo (normal saline 0.9%) ICH < 60 ml within 4.5 hours	Mortality at 7 days
Indian Trial of Tranexamic Acid in Spontaneous Intracerebral Haemorrhage	Start: 08/2022 Completion: 03/2025	4	2 grams of Tranexamic Acid in 100 ml 0.9% sodium chloride administered over 45 minutes vs control arm SBP < 140 mmHg < 4,5 h < 60 ml	Mortality 7 d
The Intracerebral Hemorrhage Acutely Decreasing Arterial Pressure Trial II (ICH-ADAPT II)	Start: 08/2011 Completion: 12/2025	2	BP to < 140 mmHg SBP or < 180 mmHg SBP during 24 h Antihypertensive therapy must begin within 6 hours of symptom onset (labetalol/hidralazine/enalapril)	DWI 48 h (ischemic lesion) Sec: ICH expansion

Target: secondary damage: neuroinflammation, PHE

Title	Start/Completion	Phase	Intervention	Primary Outcome
Efficacy and Safety of Mirabegron in Intracerebral Hemorrhage	Start: 01/2024 Completion: 11/2026	2	Standard treatment+mirabegron Vs Standard treatment the first dose of mirabegron 50mg/day will be given within 72 hours of symptom onset and continued until the 7th day after onset.	Changes in absolute perihematomal edema volume measured by computed tomography (CT)
Effects and Mechanisms of Celecoxib on Intracerebral Hemorrhage	Start: 1/2023 Completion: 07/2027	2	Early initiation of 200 mg/day celecoxib within 6 h after Deep ICH (< 30 ml) and treatment for 21 days vs control arm	Hematoma expansion volume % (day 2) Perihematomal edema (PHE) change volume % and % of participants with PHE volume change > 20% (day 2 and 7)
Biomarker and Edema Attenuation in IntraCerebral Hemorrhage (BEACH)	Start: 10/2022 Completion: 10/2026	2	Drug: MW189 (0.25 mg/kg) is administered within 24 hours of symptom onset and every 12 hours for up to 5 days (10 total doses) or until discharge (if earlier than 5 days) vs saline	Mortality < 7 days
Evaluate the Efficacy and Safety of Different Doses of Edaravone Dexborneol Concentrated Solution for Injection Combined With Conventional Medical Therapy in the Treatment of Patients With Cerebral Hemorrhage	Start: 07/2023 Completion: 06/2025	2	Multicenter, randomized, double-blind, placebo-controlled trial. The trial was divided into two periods (Period A and Period B), with Period A being a dose escalation period divided into two dose levels: the first dose level group (Dose 1 group: Synbixin 37.5 mg; placebo group) and the second dose level group (Dose 2 group: Synbixin 62.5 mg; placebo group). B safe dose vs placebo ICH within 6-24 hours in basal ganglia and volume ≤ 30 ml	SAEs < 90 days
Minocycline Accelerates Intracerebral Hemorrhage Absorption (MACHA)	Start: 01/2023 Completion: 12/2024	1	This intervention arm will receive oral or intranasal minocycline capsules 100 mg Q12H, first dose 200 mg, start on the fifth day of cerebral hemorrhage, for 14 days vs placebo 18-80 years vICH vol < 16 ml	mRS at 90 days

Target: secondary damage

Title	Start/Completion	Phase	Intervention	Primary Outcome
Studying Anakinra to Reduce Secondary Brain Damage After Spontaneous Haemorrhagic Stroke (ACTION) interleukin-1 receptor antagonist (IL-1Ra, anakinra)	Start: 08/2022 Completion: 12/2024	2	Anakinra High dose 500mg i.v. loading dose, followed by continuous iv infusion with 2mg/kg/h over 3 days Vs low dose (100mg s.c. loading dose, followed by subcutaneous administration of 100mg twice daily for 3 days.) vs conventional care ICV vol > 10 ml within 8 hours	PHE at 7 days
A Study Evaluating the Safety and Efficacy of Neuroprotective Peptide CN-105 Peptide in Patients With Acute Supratentorial Intracerebral Hemorrhage (CN-CATCH)	Start: 08/2022 Completion: 08/2024	2	Age 30 to 80 years first dose of study drug ≤ 12 hours after onset of ICH symptoms, GCS score ≥ 8 at enrollment; NIHSS score ≥ 6 Systolic BP (SBP) < 200 mmHg Intravenous infusion with CN-105 peptide for injection every 6 hours, up to a maximum of 13 doses within 72 hours.	Aes, SAEs, mortality and ICH expansion
Chinese Herbal Medicine in Acute INtracerebral Haemorrhage (CHAIN) Trial	Start: 10/2021 Completion: 01/2025	3	Chinese herbal medicine FYTF-919: Oral liquid 33ml TID (for patients who are unconscious or dysphagia, a dose of 25ml * Q6H will be given through nasal feeding) vs placebo Oral liquid 33ml TID Within 48 hours NIHSS ≥8, or b) GCS 7-14;	Utility-weighted modified Rankin scale scores. The value range from 0 to 10: higher scores mean a better outcome, at 90 days
Study to Evaluate the Safety, Tolerability and the Effects of Ixodes Ricinus-Contact Phase Inhibitor (Ir-CPI) in Adult Patients With Spontaneous Intracerebral Haemorrhage (BIRCH)	Start: 11/2023 Completion: 07/2027	2	Participants receive a single intravenous dose of Ir-CPI during 48 hours +MM vs MM ≥ 5 mL and ≤ 60 mL ICH	AEs 360 days Change in physical examination, ECG, BP, temperature, Heart rate 7 days
Reducing Edema After intraCerebral Hemorrhage (REACH trial)	Start: 03/2022 Completion: 03/2025	4	Sodium Aescinate 10mg in 250ml sodium chloride 0.9% infusion bag intravenously once daily for 10 days vs placebo ICH 10-30 ml within 24 hours	Absolute edema volume on day 14 after ICH

Target: neuroprotection, secondary damage

Title	Start/Completion	Phase	Intervention	Outcome
Statin for Neuroprotection in Spontaneous Intracerebral Hemorrhage (STATIC)	Start:08/2021 Completion: 11/2024	2-3	Atorvastatin 20 mg vs control group ICH Vol ≤40ml within 24h	Perihemorrhagic edema to hematoma ratio 7 days
Safety and Efficacy of Remote Ischemic Conditioning for Spontaneous Intracerebral Hemorrhage (SERIC-sICH)	Start:03/2024 Completion: 06/2025	NA	Remote ischemic conditioning (RIC) is induced by 4 cycles of 5 min of healthy upper limb ischemia followed by 5 min reperfusion. Limb ischemia was induced by inflations of a blood pressure cuff to 200 mm Hg. RIC will be conducted twice daily for 7 days +MM vs Sham remote ischemic conditioning (Sham RIC) is simulated by the measurement of blood pressure twice daily for 7 days + MM NIHSS score ≥ 4 and GCS ≥ 6 upon presentation < 12 hours symptoms onset	mRS 0-2 at 90 days
Feasibility Study of Transcranial Ultrasound Stimulation (TUS) on Stroke Patients	Start:07/2021 Completion: 12/2024	NA	Transcranial ultrasound stimulation 4 weeks and rehabilitation therapy vs RHB therapy Hypertensive deep ICH, 20 and 65 years, 3 to 12 months after ICH	Brain atrophy and changes in vessels on MR-angiography at 12 weeks
Safety and Efficacy of Remote Ischemic Conditioning for Spontaneous Intracerebral Hemorrhage	Start:02/2023 Completion: 05/2025	NA	Remote ischemic conditioning is induced by 4 cycles of 5 min of healthy upper limb ischemia followed by 5 min reperfusion. Limb ischemia was induced by inflations of a blood pressure cuff to 200 mmHg vs Sham remote ischemic conditioning (Sham RIC) is induced by 4 cycles of 5 min of healthy upper limb ischemia followed by 5 min reperfusion. Limb ischemia was induced by inflation of a blood pressure cuff to 60 mm Hg. NIHSS score ≥ 6 and GCS ≥ 8 within 24 hours of stroke onset, SBP ≤ 180	mRS Score 0-2 180 days
Effect of Cilostazol in Promoting Hematoma Clearance After Intracerebral Hemorrhage	Start: 08/2024 Completion: 05/2027	2	Two consecutive weeks of oral Cilostazol (50mg BID) two days after admission vs Conventional internal medicine treatment Deep ICH, ICH score less than 3 (hematoma volume no greater than 15 ml) within 24 hours	ICH volume at 16 days

Target: neuroinflammation, neural regeneration (stem cells transplantation)

Title	Start/Completion	Phase	Intervention	Primary Outcome
Phase I/II Trial of Intracerebral Transplantation of Autologous Bone Marrow Stromal Cells Combined With Recombinant Peptide Scaffold for Patients With Chronic Intracerebral Hemorrhage (RAINBOW-Hx)	Start: 12/2023 Completion: 2/2026	1 and 2	Drug: HUFF-01autologous MSC combined with scaffold The goal of this clinical trial is to test intracerebral transplantation of stem cell product in patient with chronic intracerebral hemorrhage (safety and efficacy) through stereotactic transplantation into the hemorrhagic cavity. Age 20-70 years, Deep ICH > 12 months and mRS 3-4	Number of participants with treatment-related adverse events as assessed by CTCAE v5.0 Secondary outcomes: change in mRS, NIHSS, FIM, Fungl-Meyer...
Neurologic Bone Marrow Derived Stem Cell Treatment Study	06/2026 07/2025	NA	Single Group Assignment Autologous Bone Marrow Derived Stem Cells provided intravenous and intranasal (lower 1/3 of nose) Patients with functional damage to the central or peripheral nervous system unlikely to improve with present standard of care. Be at least 6 months post-onset of the disease, including ICH patients	Neuro-QOL at 1,3,6 and 12 months post treatment
Stromal Vascular Fraction (SVF) Therapy in Patients With Acute Spontaneous Intracerebral Hemorrhage (SI CH).	03/2022 06/2024	1	3 dose of SVF 0.5/1/1.5 x 10 ⁶ /kg Intravenous infusion (IV) within 1 month after ICH surgical evacuation The active treatment is an intravenous injection with the stromal vascular fraction (SVF) harvested from the patient's own fatty tissue 45-55 years Stable ICH< 60 ml	AEs 1 year

Target: general care

Title	Start/Completion	Phase	Intervention	Primary Outcome
International Care Bundle Evaluation in Cerebral Hemorrhage Research (I-CATCHER)	09/2024 03/2027	4	<p>Intervention group:</p> <ul style="list-style-type: none"> -Reversal of Oral anticoagulation within 30 minutes to reach and maintain an INR target <1. -Early intensive blood pressure lowering: 130-140 mmHg within 30 minutes and for the first 7 days (for patients presenting with blood pressure <200 mmHg). If blood pressure ≥200 and <220, a target BP of 160 mmHg should be targeted at 30 minutes, and 130-140 mmHg should be achieved in 60 minutes. If BP ≥220, target BP of 160 mmHg and should be achieved in 60 minutes. -Treatment of piroxia to achieve a body temperature target <37.5 °C -Hyperglycemia treatment to maintain a blood glucose level 7-10 mmol/L -Do-not-resuscitate (DNR) or withdrawal of care for 48 hours -Referral to Intensive Care Immediate (<30 min) if airway, breathing and/or circulation are compromised -Referral to Neurosurgery Immediate (<30 min) if any of the following criteria are fulfilled: <ul style="list-style-type: none"> -Large and/or rapidly evolving supratentorial ICH (>20 ml volume) -Any intraventricular extension -Posterior fossa bleed, irrespective of volume -Suspicion of a vascular malformation, independent of volume or location -Reduction in reaction to sensory stimulation or drowsiness -Repeat brain imaging 6-12 hours <p>vs Control group, clinical decisions according to treating clinical team</p>	mRS at 180 days
PROpranolol for Cerebral Hemorrhage-Associated pneumonia (PRO-CHASE)	02/2023 07/2025	2	<p>Propranolol hydrochloride will be administered intravenously via pump at a initial dose of 5mg/day over a course of 7 consecutive days after randomization vs conventional treatment</p> <p>HIC < 24 h NIHSS 11-25 ICH vol> 10 ml No infection signs</p>	Incidence of stroke-associated pneumonia < 7 days

Target: recovery

Title	Start/ completion	Phase	Intervention	Primary outcome
Efficacy and Safety Study: Repetitive Transcranial Magnetic Stimulation (rTMS) for Treating Movement Disorders in Patients With Intracranial Hemorrhage (ICH)	07/2023 12/2024	NA	<p>Repetitive Transcranial Magnetic Stimulation with Magstim Rapid 2 magnetic stimulation device Vs sham control with Magstim Rapid 2 magnetic stimulation device</p> <p>1 to 3 months after Deep ICH 30-60 ml and moderate to severe motor functional impairment, and underwent surgical treatment for ICH within 2 weeks after the event, utilizing either craniotomy or endoscopic hematoma evacuation, with an evacuation rate of at least 80%.</p>	Fugl-Meyer Assessment (FMA) at 6 months
The Effect of Music Listening in Rehabilitation of Subacute Stroke	08/2024 12/2026	NA	The control group gets standard rehabilitation. Music group gets standard rehabilitation and in addition they listen to music one hour a day during four weeks hemispheric stroke (ischemic or intracerebral hemorrhage) during last 4 weeks OR spinal cord injury in last 6 months, causing a need of intensive rehabilitation	Change in limb function, speech, mood and daily functions at 0 and 4-5 weeks
Acceptance and Commitment Therapy-based Group Therapy for Mental Health After Stroke - a Pilot Study	07/2024 01/2025	NA	To test the feasibility, acceptance and preliminary efficacy of an adapted group psychotherapy manual in stroke survivors with psychological stress. Open label. Value above a cut-off on one of the DASS-21 subscales (depression > 10, anxiety > 6, and stress > 10)	Drop out rate, session adherence, depression and Anxiety Stress Scales-21

Target: secondary prevention

Title	Start/Completion	Phase	Intervention	Primary Outcome
MOBILE Health Intervention in IntraCerebral Hemorrhage Survivors (MOBILE-ICH)	Start:10/2023 Completion: 03/2026	NA	Patients will be randomized into mobile health intervention (MOBILE) and the usual care group for hypertension management . All subjects will be educated on the importance of hypertension control after ICH and given lifestyle advice, including the DASH diet. Subjects in the MOBILE group will enter their home blood pressure (BP) measurements into a mobile stroke App (WeRISE) daily, and the study team will regularly review the BP measurements through a backend system. A protocol-based intervention via phone calls, which includes anti-hypertensive drug adjustment and reinforcement of lifestyle modification, will be implemented. Subjects in the usual care group will have their hypertension managed by their respective treating physicians. All subjects will be followed up for 26 weeks.	Rate of controlled hypertension 12 weeks after ICH Office BP <130/80 mmHg
Statins In Intracerebral Hemorrhage (SATURN)	Start:06/2020 Completion: 12/2026	3	Patients presenting within 7 days of a spontaneous lobar ICH while taking statins will be randomized to one of two treatment strategies: discontinuation vs. continuation of statin therapy (using the same agent and dose that they were using at ICH onset). Participating subjects will undergo baseline testing for APOE genotype and will be followed for 24 months to assess for the occurrence of recurrent symptomatic ICH or major adverse cerebro-/cardio-vascular events (MACCE) during the follow-up period. Age > 50 years	Recurrent symptomatic ICH 24 months
Avoiding Anticoagulation After IntraCerebral Hemorrhage (A3ICH)	Start:01/2029 Completion: 12/2026	3	Open label randomised controlled multicentre clinical trial with masked outcome assessment (PROBE design) comparing 3 strategies (1:1:1): anticoagulation with a Direct OAC (Apixaban 5mgx2/day) vs avoid anticoagulation with left atrial appendage closure (LAAC) compared to usual care (avoid anticoagulation).	Composite of all fatal or non-fatal major cardiovascular/cerebrovascular ischaemic or haemorrhagic intracranial/extracranial events within 24 months
Anticoagulation in ICH Survivors for Stroke Prevention and Recovery (ASPIRE)	Start: 01/2020 Completion: 04/2027	3	To determine if apixaban is superior to aspirin for prevention of the composite outcome of any stroke (hemorrhagic or ischemic) or death from any cause in patients with recent ICH and atrial fibrillation (AF).	Stroke or death up to 3 years

Target: secondary prevention in CAA

Title	Start/Completion	Phase	Intervention	Primary Outcome
A Phase 2 Trial of ALN-APP in Patients With Cerebral Amyloid Angiopathy (cAPPicorn-1)	Start: 05/2024 Completion: 11/2029	2	To evaluate the effect of intrathecally ALN-APP (mivelsiran) on measures of CAA disease progression and to characterize the safety, tolerability, and pharmacodynamics of ALN-APP in adult patients with sporadic CAA (sCAA) and Dutch-type CAA (D-CAA) vs placebo intrathecally. The study will be conducted over 2 periods: a 24-month double-blind treatment period and an optional 18-month open-label extension (OLE) period.	Annualized Rate of New Lobar Cerebral Microbleeds (CMBs) Assessed on Magnetic Resonance Imaging (MRI) of Brain in Patients with Sporadic Cerebral Amyloid Angiopathy (sCAA) up to 24 months
Antibiotics Against Amyloid Angiopathy (BATMAN)	Start: 12/2020 Completion: 12/2023	1-2	Minocycline 100 mg twice daily for 3 months vs placebo in patients with Probable-CAA according to the Modified-Boston-Criteria or genetically proven D-CAA	IL6, MCP-1, IBA-1, MMP2/9, and VEGF at 3 months
Stimulating Amyloid Clearance in Cerebral Amyloid Angiopathy (Clear-Brain)	Start: 06/2024 Completion: 08/2026	2	Low-sodium oxybate, Non-invasive vagus nerve stimulation or a combination of both interventions can enhance the clearance of A β in patients with CAA Patients with D-CAA with a proven amyloid precursor protein (APP) mutation or a history of ≥ 1 lobar intracerebral haemorrhage (ICH) and a positive family history for D-CAA in ≥ 1 first degree relative Probable sporadic CAA (sCAA) according to the Modified Boston criteria 2.0 Age ≥ 50 years old ≤ 2 symptomatic ICH (occurrence of ICH at least > 1 year ago) Provisional CAA	Amyloid-beta 40 and 42 in cerebrospinal fluid at 3 months

Conclusions



MULTIPLE CLINICAL TRIALS ARE
BEEN PROVED OR ARE GOING TO
START FOR ICH



TARGET: SURGICAL EVACUATION
BY MINIMALLY INVASIVE
SURGERY AND
NEUROINFLAMMATION



MULTIMODAL APPROACHES



SECONDARY PREVENTION OF
CEREBRAL AMYLOID
ANGIOPATHY ICH HAS EMERGING
AS A TARGET IN CLINICAL TRIALS



UNITAT D'ICTUS

HOSPITAL UNIVERSITARI
Dr. JOSEP TRUETA
de GIRONA

- Many thanks to patients and families for their generosity in the inclusion in clinical trials
- And to the colleagues who, despite the intense work, continue to dedicate efforts to include patients in clinical trials and to our laboratory colleagues for continuing to investigate new molecules and animal models
- Our team invites you to the 4th edition of the race “Run for stroke” on November 24th this year in Girona

