Supplementary material BMJ Open

Additional File 2: Summary of the FINISH trial protocol

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT04203550
Date of registration in primary registry	December 18, 2019
Secondary identifying numbers	N/A
Source(s) of monetary or material support	State funding for University-level health research (Helsinki University Hospitals), Finska Läkaresällskapet, Medicinska Understödsföreningen Liv & Hälsa
Primary sponsor	Helsinki University Hospital
Secondary sponsor(s)	N/A
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Public title	Irrigation or no irrigation for surgery of chronic subdural haematoma (FINISH)
Scientific title	The Finnish study of Intraoperative Irrigation versus drain alone after evacuation of chronic Subdural Haematoma (FINISH): A study protocol for a multicentre randomised controlled trial
Countries of recruitment	Finland
Health condition(s) or problem(s) studied	Chronic subdural haematoma (CSDH)
Intervention(s)	Active comparator: Irrigation (i.e. the subdural space is irrigated by repeated rinsing with body temperature saline solution with a syringe and blunt needle until surgeon considers exudate to be clear. The minimum volume of irrigation is 200 ml per operated side. A subdural drain is inserted 3–5 cm underneath the skull and parallel to it and kept as a passive drain for 48 hours) Experimental: No irrigation (i.e. after a small incision of the dura, a subdural drain is inserted 3–5 cm underneath the skull and parallel to it and kept as a passive drain for 48 hours)

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Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: ≥18 years Sexes eligible for study: All Accepts healthy volunteers: No Inclusion criteria: Patients with a symptomatic unilateral or bilateral CSDH requiring burr-hole evacuation Predominantly hypodense or isodense on imaging (CT/MRI) Clinical symptoms correlating with CSDH Patients with bilaterally operated CSDHs will be treated with the same protocol on both sides and analysed as a single study participant Exclusion criteria: CSDH requiring surgical treatment other than burr-hole evacuation (e.g. craniotomy) CSDH in a patient who has a cerebrospinal fluid shunt Patients who have previously undergone any intracranial surgery Comatose patients (GCS 8 or lower) with absent motor responses to painful stimuli; decerebrate or decorticate posturing Patient's postoperative cooperation is suspected to be insufficient for drain usage (i.e. disoriented or semiconscious patient) Patient has a haematogenic malignancy that has been actively treated within the previous five years Patient has a central nervous system tumour or malignancy Patient has a nacute infection requiring antibiotic treatment Patient has a high risk of life-threatening thrombosis (e.g. recent coronary stent, intracranial stent, recent pulmonary embolism, low pressure cardiac valve replacement [mitral- or tricuspid valve replacement]) and discontinuation of antithrombotic medication is not recommended
Study type	Prospective, randomised, controlled, parallel group, non-inferiority trial Allocation: Randomised Intervention model: Parallel assignment Intervention model description: Prospective, randomised, controlled, parallel group, non-inferiority trial Masking: Quadruple (participant, care provider, investigator, outcomes assessor) Primary purpose: Treatment
Date of first enrolment	January 2020

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Target sample size	540 participants
Recruitment status	Recruiting
Primary outcome(s)	Rate of reoperations of ipsilateral chronic subdural hematoma (time frame: 6 months from randomization)
Key secondary outcomes	Change of Modified Rankin Scale (time frame: 6 months), rate of mortality (time frame: 6 months), duration of operation, hospital length of stay, rate of adverse events (time frame: 6 months), change in volume of CSDH between baseline and 2 months