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Middle meningeal artery (MMA) embolisation for chronic subdural haematomas: rationale and design for the STOp Recurrence of MMA Bleeding (STORMM) randomised control trial—a study protocol

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ABSTRACT

Introduction Chronic subdural haematomas (cSDH) are common and can result in neurological impairment and reduced consciousness. Surgery is typically performed once neurological symptoms develop. Recent studies suggest that arteries nourished by the middle meningeal artery (MMA) may be responsible for haematoma progression and that MMA embolisation is clinically useful. There is less evidence that MMA embolisation can be an option for individuals without surgical treatment. We propose a multicentre study to investigate the efficacy of MMA embolisation to reduce cSDH recurrence and to improve outcomes.

Methods and analysis cSDH patients with surgical indication will be randomised between the conventional management group (ie, surgery alone without MMA embolisation, Arm 1) and the surgery followed by MMA embolisation group (Arm 2) at multiple centres within Switzerland and Europe. The primary outcome will be the recurrence rate of cSDH. For that purpose, we estimate a minimum enrolment of 156 patients (alpha=0.05, power of 80%). Other major outcomes will include radiological parameters (volume, haematoma size, unilateral/bilateral presence) as well as clinical outcome scales and readmission rates. Outcomes will be recorded at admission and 6 weeks' and 6 months' follow-ups. Embolisation alone will be proposed to unoperated patients (surgical contraindication or refusal of surgery); the group of patients accepting and receiving embolisation (Arm 3) will additionally be compared with the group of untreated patients (Arm 4).

Ethics and dissemination While it has been suggested that MMA embolisation reduces recurrence, no high-level evidence exists. As low risks exist with neuro-interventional procedures, there is equipoise for randomising patients to evaluate the potential benefits of MMA embolisation and to determine if these clearly outweigh the risks and costs. Peer-reviewed publications and presentations of the results at international meetings are planned.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ There are currently no published multicentre randomised controlled studies investigating the efficacy of MMA as an adjunct to surgical treatment for cSDH.
⇒ The study has the potential to drastically improve the treatment options of patients with cSDH, who frequently suffer from recurrence, partially due to the fact that these patients are often under antithrombotic treatment for other causes.
⇒ The secondary objective of the study is to determine whether MMA embolisation alone can be a therapeutic option to stop cSDH progression for patients who cannot be treated by surgery.
⇒ MMA embolisation is a recently described technique for which large trials have not yet been published, and the balance of risks and benefits of this procedure remains unknown.
⇒ Given the benefit of previous non-randomised reports published in the literature, the main limitation of this study would be that patients refuse to be randomised for fear of being categorised into a control group despite our 2:1 ratio for embolisation.

Trial registration number The protocol is approved by the Geneva and Ticino Ethics Commission for Research (2023-00848) and is recorded on clinicaltrials.gov (NCT06163547).

INTRODUCTION

Chronic subdural haematoma (cSDH) is one of the most frequently encountered pathologies in neurosurgery, presenting typically in the elderly population. The condition is often preceded by a history of a relatively minor trauma to the head, usually weeks before the

onset of neurological symptoms. Patients can present with a wide set of neurological symptoms which typically include a reduced state of consciousness and confusion. The most important risk factors associated with cSDH development include antithrombotic medication use, male gender and craniocephalic disproportion often as a consequence of alcohol abuse, cerebral atrophy or both.[1] Treatment for cSDH is typically undertaken once a patient becomes symptomatic and is classically performed by burr hole drainage of the haematoma, which resolves symptoms in a relatively rapid fashion.

cSDHs are known for their frequent recurrence, with estimates in the literature currently approximating a rate of between 9 and 33%.[2–6] While the exact pathophysiology of the initial haematoma formation is not fully understood, it is believed that the shearing of veins at the dural cell layer is the initiating event, while neovascularisation in the ensuing inflammatory response is thought to be nourished by branches of the middle meningeal artery (MMA).[1] As a consequence, recent studies have shown that the embolisation of the MMA can result in lower rates of recurrence, with a recent systematic review showing a composite recurrence rate of only 3.6%.[7] The ramifications of such a drastic decline in rates of recurrence include a need to re-operate individuals, who often require antithrombotic medication for other medical conditions. However, evidence to support the benefit of MMA embolisation is limited and the risk-benefit balance remains unclear. Theoretically, the complications of such a procedure would include arterial access tear resulting in dissection or excessive bleeding, stroke, embolisation extending to possible dangerous collaterals such as the ophthalmic artery, and radiation-associated complications. However, the complication rate of MMA embolisation is poorly documented in the literature and probably extremely low. Indeed, one systematic review of the safety and effectiveness of embolisation in cSDH including 193 MMA embolisations across 15 studies reported no complication of the procedure.[8] The potential efficacy and safety of MMA embolisation as a treatment therefore require higher levels of evidence in the form of randomised controlled trials.

In this paper, we present the research protocol for a prospective multicentre randomised controlled trial designed to investigate the efficacy of MMA embolisation as an adjunct treatment for patients undergoing surgical intervention for cSDH. Specifically, patients who require surgical treatment for cSDH will be randomised to receive either MMA embolisation following their surgery or standard surgical management without embolisation. The primary outcome of the study is to compare the recurrence rates of cSDH between those receiving MMA embolisation combined with surgery and those undergoing surgery alone. We hypothesise that the addition of MMA embolisation will significantly reduce the recurrence of cSDH in this patient population.

The secondary outcome is to assess the potential benefit of MMA embolisation-only treatment for patients who have a surgical indication but cannot undergo surgery (due to personal or medical reasons). With this subgroup, it is hypothesised that MMA-embolisation will prevent the progression of cSDH.

Table 1 Key inclusion and exclusion criteria

cSDH with surgical indication	
Inclusion criteria	**Exclusion criteria**
► Age: 18–100 ► Consent possible ► cSDH located at the convexities ► Patients with symptomatic cSDH ► Patients with asymptomatic large chronic/subacute haematoma after 6 weeks of failed conservative treatment	► Consent not possible ► Pregnancy ► Prisoner ► Angiography contraindication ► Patient for whom follow-up is problematic (eg, distant residency, homelessness…) ► Previous surgery for cSDH

cSDH, chronic subdural haematoma.

METHODS AND ANALYSES

For the writing of this clinical trial protocol, we used the SPIRIT reporting guidelines.[9]

Study population

Participants will include adults aged 18 to 100 years with unilateral or bilateral cSDH located at the convexities who meet the criteria for surgical intervention. Eligible cases may be symptomatic or, if asymptomatic, must have a large chronic or subacute haematoma persisting after 6 weeks of failed conservative management. Inclusion requires the possibility of obtaining consent, either from the patient or from their legal representative. Exclusion criteria include patients unable to provide or obtain consent, pregnant individuals, prisoners, those with contraindications to angiography, individuals for whom follow-up would be challenging (eg, those with distant residency or homelessness) and patients with a history of prior surgical treatment for cSDH. The inclusion and exclusion criteria are outlined in table 1 and figure 1. Patient demographic characteristics will be collected as well as notable comorbidities (including COVID infection), the use of steroids, use of antithrombotic medication, smoking status, alcohol abuse, history of trauma, COVID vaccination status (and time of vaccination). In addition, a Charleston comorbidity index score will be attributed to all patients.[10]

The study will be undertaken at multiple trauma centres in Switzerland, mainly in Geneva and Lugano, with the aim to extend the recruitment of patients across Europe with the objective to enrol patients within an 18–24-month timeframe. With the last follow-up planned at 6 months, the combined study duration is expected to be no longer than 24–30 months. The recruitment is planned to start

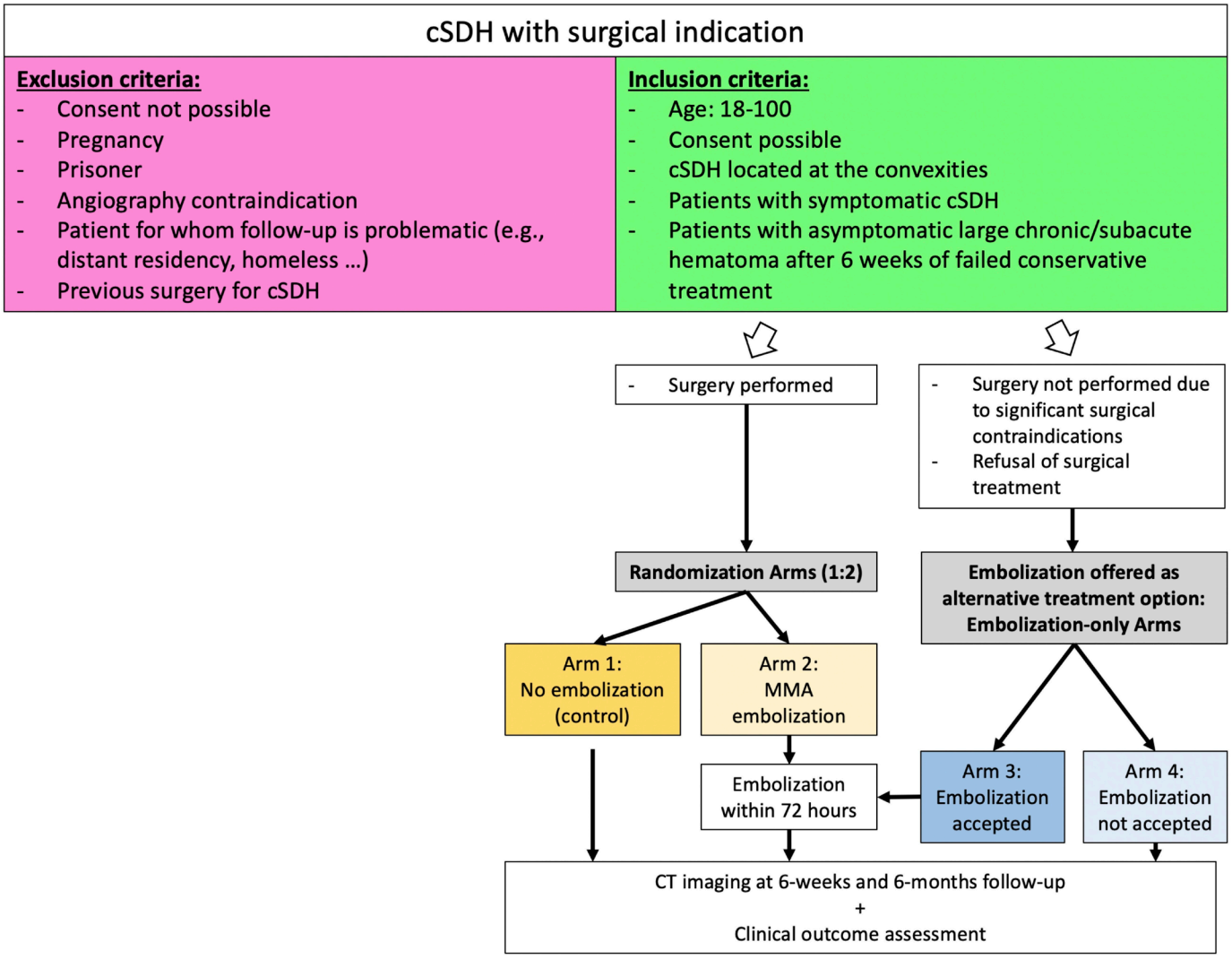

Figure 1 Clinical pathway of the study. cSDH, chronic subdural haematoma; MMA, middle meningeal artery.

on 1 February 2025, and therefore, the end date for the study is expected to be between 31 December 2026 and 30 June 2027.

Interventions and conditions description

Patients who undergo surgical treatment will be randomised into conventional management without embolisation (Arm 1) or receiving embolisation within 72 hours of surgery (Arm 2). Patients will be randomised at a rate of two MMA embolisations to one conventional management. We estimate that with a 2:1 randomisation ratio, there will be an increase in chances to show a significant effect of MMA embolisation if there is one. The aforementioned patient collected data (see 'Study population') will not affect randomisation and, with a sufficient sample size, we expect to end up with comparable groups.

We favour postoperative rather than preoperative embolisation for organisational reasons within our institutions and to include patients requiring very urgent surgery. Indeed, in the latter case, while urgent surgery may be necessary for large haematomas and/or acute/subacute neurological deficits or reduced levels of consciousness, MMA embolisation's effect is not expected to be direct and may wait until the patient is operated.

Patients who are excluded from surgery due to significant medical contraindications (eg, severe thrombocytopenia or double anti-thrombotic therapy without imminent danger of death) or patients who refuse surgery will be considered for embolisation only. In this group, patients consenting to the embolisation will be part of Arm 3 and patients refusing embolisation will be part of Arm 4 (for a summarising diagram of the different study arms, see online supplemental appendix 1).

The surgical treatment and the embolisation procedure will be standardised among doctors and centres for better reproducibility.

All the neurosurgery consultants as well as neurosurgical residents (under supervision) of each centre will be able to perform the cSDH evacuation surgery. Surgery is performed in a semi-lateral position with the head held horizontal on a horseshoe head rest. Two skin incisions are made for one burr hole in each, one close to the

coronal suture and the other one 8 cm posteriorly in the parietal region, both dorsal to the superior temporal line. The dura is then coagulated and opened, and the haematoma is evacuated. The subdural compartment is abundantly washed with a saline solution until the fluid comes back clear. A siphoning subgaleal drain is put in place and the skin is closed in a fashion to minimise air entrapment in the subdural space. The patient thereafter stays in a strict bedrest at 0° inclination for 48 hours and the drain is removed on the second postoperative day.

Regarding MMA embolisation, all the board-certified interventional neuroradiologists of each centre will be able to perform the intervention. MMA embolisation is performed with the use of biplane digital subtraction angiography. The type of anaesthesia is at the discretion of the operator. The site of peripheral arterial access and the type of catheters are at the discretion of the operator based on their experience and the vascular anatomy. Before embolisation, angiographic images of the intracranial circulation must be acquired for the internal (ICA) and external carotid arteries (ECA), or the common carotid artery (CCA). Then, the tip of the guiding catheter or of an intermediate catheter is advanced in the ECA. The microcatheter is selectively navigated under roadmap guidance into the MMA, and superselective angiography is performed prior to embolisation to evaluate for potentially dangerous collateral vessels such as ophthalmic, carotid siphon, and petrous branches. Then, the operator proceeds to embolisation of the target MMA by injection of small-calibre microparticles or liquid embolics. If particles are used, they must be of a calibre ≤300 µm, as there is evidence that the 300–500 µm Embosphere (Merit Medical, South Jordan, Utah, USA) tris-acryl gelatin microsphere (TAGM) particles are not effective in preventing the recurrence of cSDH (oral presentation of the EMPROTECT trial results at the ESMINT 16th Congress 2024[11]). In the event of an identified dangerous anastomosis on the superselective angiogram of the MMA, either the anastomosis is secured by coiling or the artery is embolised downstream of the anastomosis with a sufficient security margin. Success is defined as both frontal and parietal branches being embolised selectively or through the main trunk of the MMA. Intravenous heparin administration during the procedure will be recorded. At the end of the procedure, control angiographic images of the intracranial circulation must be acquired for the ICA and ECA, or the CCA. A cone-beam computerised tomography may be performed at the end of the procedure.

Regarding potential antithrombotic medications, these will be resumed depending on their initial indication, after assessing the risk-benefit balance. In the case of primary prevention with a reasonable risk to suspend the drug, then the treatment will be withheld at least until the 6 weeks' follow-up where a new risk-benefit balance assessment will be made. In case of secondary or tertiary prevention with a high risk of drug suspension, then the treatment will be resumed earlier after a discussion with the specialist (neurologist, cardiologist, cardiovascular surgeon or interventional radiologist) who introduced the drug.

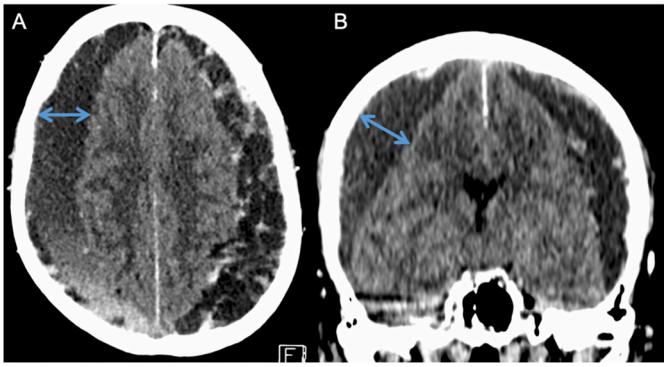

Figure 2 CT imaging of a bilateral chronic subdural haematoma (cSDH). Axial view (A) and coronal view (B) showing the maximal diameter of the cSDH. Blue arrows indicate the axial and coronal widths of the cSDH.

Primary and secondary outcome measures

The study will use a combination of clinical, radiological and functional outcome measures to assess differences between the two study groups. The clinical finding of recurrence represents the primary outcome measure of the study. A recurrence is defined as a cSDH reappearance that requires surgical reoperation, a neurological deterioration due to a cSDH after evacuation, or a postoperative haematoma volume of more than 90% of the preoperative volume at follow-up. Recurrence of unilateral and bilateral haematomas will be recorded. The radiological assessment includes volume, maximal coronal and axial haematoma size, and degree of midline shift for unilateral cSDHs, as measured on CT imaging at the 6 weeks' and 6 months' follow-ups (figure 2, online supplemental appendix 2). Additional outcome measures will include the Glasgow Coma Scale, modified Rankin Scale, Karnofsky score, Markwalder grade and the Glasgow Outcome Scale-Extended.[12–15] The occurrence of mortality, complications via the Therapy-Disability-Neurology grading system[16] and readmission will likewise be monitored during the study period. The recommencement of antithrombotic medication for patients under such treatment will be noted at the time of discharge, and each follow-up period. The collection of data points is listed in table 2.

Secondary objective: efficacy of MMA embolisation in isolation for stopping cSDH progression

For patients receiving embolisation-only treatment, the follow-up schedule remains the same as that outlined in table 2 for the randomised cohort. Likewise, the same radiological parameters will be assessed. However, the radiological definitions of haematoma 'regression', 'stability' and 'progression' are defined as >10% reduction in volume, ±10% of previous volume and >10% increase in haematoma volume. Furthermore, the presence and proportion of 'acute' components of the haematoma will

Table 2 Data collection periods

Measure	Admission	Discharge	6 weeks	6 months
Glasgow Coma Scale	√	√	√	√
Modified Rankin Scale	√	√	√	√
Markwalder Grade	√	√	√	√
Glasgow Outcome Scale-Extended		√	√	√
Karnofsky	√	√	√	√
Therapy-Disability-Neurology grading system		√	√	√
CT parameters including (unilateral/bilateral), volume, maximum axial size, maximum coronal size, degree of midline shift for unilateral chronic subdural haematoma	√		√	√

be noted (acute component of >75%, 50–75%, <50% and >25%, 25% or less, 0%).

MMA economic utility assessment subanalysis

The overall cost, including the embolisation procedure, changes in length of hospital stay and complications related to embolisation, will be weighed against costs associated in the changes in recurrence rates (including reoperations and hospital stays related to reoperations).

Statistical analysis—randomised cohort

The incidence rate of cSDH recurrence is estimated at 20% and recurrence with MMA embolisation at 5%. With an alpha=0.05 and power of 80%, we estimate that a minimum of 156 patients will need to be enrolled (https://clincalc.com/stats/samplesize.aspx). Assuming a 15% loss of follow-up, 180 patients will need to be enrolled in the study. It is therefore planned to enrol 180 patients. Comparison of recurrence rate between the groups will be assessed via logistic multivariate analysis where recurrence is the dependent variable, and sex, presence of unilateral/bilateral cSDH, treatment with antithrombotic medication, alcohol abuse status, age and cerebral atrophy will be considered as independent variables.

The random assignment of participants to conventional treatment (Arm 1) or MMA embolisation (Arm 2) will be achieved using a block randomisation method stratified by centre (Geneva, Lugano). Random block sizes will be used. To maintain the concealment of the allocation principle, block sizes will only be revealed in the statistical analysis plan (PAS) once enrolment is ended. For each centre, the randomisation list will respect a 2:1 ratio (two MMA embolisations for one conventional management). Expecting a higher capacity of patient enrolment in Geneva, the randomisation lists will be of different sizes:

- The randomisation list will be of size n=120 in Geneva (n=40 in Arm 1, n=80 in Arm 2).
- The randomisation list will be of size n=60 in Lugano (n=20 in Arm 1, n=40 in Arm 2).

Randomisation will be computer generated with the R software. The seed allowing the reproduction of the randomisation plan will be stored in the programming file of the software (R script).

Concealment mechanism—randomised cohort

The allocation concealment mechanism for the randomised cohort will be using sealed envelopes. The list implementation will be generated by the Clinical Research Center (CRC)'s methodological unit and sent to a person external to the study who will prepare the envelopes.

Statistical analysis—isolated MMA embolisation cohort

This part of the study is inherently exploratory, and it is not possible to estimate how many people will fall into this category as this is not yet a standardised treatment. The benefits of embolisation (Arm 3) will be compared with patients who are eligible for embolisation only but do not receive this treatment (the patient or his/her caregivers do not wish it) and are only followed-up clinically (Arm 4). If the cohort size permits, changes in outcomes (changes in volume progression, mortality and readmission) between these two groups will be assessed with univariate and multivariate analyses. Outcomes will include regression or stability versus progression, as well as the presence and proportion of acute haematoma. Enrolment for this portion of the study will terminate once the recruitment goal of the randomised portion of the study will be attained. In case of an insufficient number of recruited patients in Arms 3 and 4 for statistical analysis, the data will be presented descriptively.

Handling of missing data and drop-outs

Data obtained until the dropout will be kept unless the patient refuses. If interpretable, they will be analysed. Missing data will not be imputed or replaced; patients with missing data will be excluded from analyses for the primary objectives; however, this data may be used for subsequent secondary analyses if interpretable.

Patient and public involvement

No patient and public involvement are planned for this study.

DATA PROTECTION

Data recording and source data

The investigators will manage the data which will be treated confidentially according to the rules of medical

secrecy. The data of each patient will be reported in a dedicated electronic Case Report Form (eCRF) (online supplemental appendix 3) and encoded. The same code will be assigned to the source data containing the patient's parameters. The CRFs will be kept in the Neurosurgery Departments until the end of the study. For security and storage issues, data will be transcribed and coded in a Research Electronic Data Capture (REDCap) database that will be created specifically for this study. The principal investigator and secondary investigators will keep the code key.

Confidentiality and coding

Study data will be collected from the CRFs. Patient names will be replaced by a study participation number (code). Only investigators actively involved in the study will know the identity of the patient. Subjects will be informed that their personal data may be made available in the event of an audit or inspection by regulatory authorities, in a confidential manner and for the purpose of verifying the application of the ethical principles of Good Clinical Practice in the context of a research protocol. In case of publication, the results will be expressed in a collective manner and no patient will be identifiable.

The type of coding is quantitative. The software used for coding and archiving will be the REDCap database, a Swiss Clinical Trials Data Management system (CTDMS) already widely used in our institution.

Retention and destruction of study data

All study data are archived for 10 years after study termination or premature termination of the study.

Data accessibility

The dataset is available upon demand from the REDCap database.

MONITORING, REGULATORY ASPECTS AND SAFETY

Monitoring institutions

For the Geneva University Hospitals (HUG), the institution that will perform the monitoring duties of this study is the Clinical Research Center of the HUG. Performed monitoring will be:

- Site initiation visit;
- Routine visit at 5% patient's inclusion: full source data verification (SDV).
- Routine visit at 50% of remaining patients: partial SDV-key data.
- Close-out visit.

For the Neurocenter of Southern Switzerland, the institution that will perform the monitoring duties of this study is the Clinical Trial Unit of the Ente Ospedaliero Cantonale. Performed monitoring will be:

- Site initiation visit.
- Routine visit at 10% patient's inclusion: full SDV.
- Routine visit at 40% patient's inclusion: partial SDV-key data.
- Routine visit at 70% patient's inclusion: partial SDV-key data;
- Close-out visit.

Follow-up of (serious) adverse events

The patient population on average is considered very old (70–80 years) and presents with a condition requiring surgery. Therefore, the possibility of SAE regardless of embolisation is considered high. We will note the record cases of mortality, re-operation within 6 months and embolisation-related complications, and undertake an interim analysis after 50% of study enrolment. As this would result in an estimated 60 patients (30 of 90 enrolled) receiving embolisation, this sample size should be sufficient to determine if there is a significant increase in adverse events. Monitoring for adverse events will be undertaken continuously, and if it is deemed that there is a disproportionate number of adverse events that are occurring prior to the interim analysis, an earlier case analysis may be sought under such an exceptional circumstance. The management and reporting of adverse events will be guided by the Clinical Research Center at HUG (for the SAE report form, see online supplemental appendix 4).

Notification of safety and protective measures

If immediate safety and protective measures have to be taken during the conduct of the study, the investigator will notify the Ethics Committee of these measures, and of the circumstances necessitating them, within 7 days.

Premature termination of study

The Sponsor-Investigator may terminate the study prematurely according to certain circumstances, for example,

- Ethical concerns.
- Insufficient participant recruitment.
- When the safety of the participants is doubtful or at risk (eg, when the benefit-risk assessment is no longer positive);
- Alterations in accepted clinical practice that make the continuation of the study unwise;
- Early evidence of harm or benefit of the experimental intervention.

ETHICS AND DISSEMINATION

While it has been suggested that MMA embolisation reduces recurrence, this has not yet been demonstrated with high-level evidence. Furthermore, there are some risks, although infrequent, associated with neurointerventional procedures, and therefore there is equipoise for randomising patients to evaluate the potential benefits of MMA embolisation and to determine if these clearly outweigh the risks and costs.

For the second part of the study, entailing treatment with embolisation only (Arms 3 and 4), there is scant evidence to support that such a treatment without preembolisation surgery will stop cSDH progression. Nevertheless, given that these patients do not have the option of surgery, the benefit of an embolisation may potentially

be life-saving. However, this remains to be studied, and therefore, patients and/or their caregivers need to be clearly informed of the potential benefit as well as potential futility of such a procedure.

The protocol is approved by the Geneva and Ticino Ethics Commission for Research (authorisation number 2023-00848) and is recorded on clinicaltrials.gov (NCT06163547) (the trial registration information is summarised in the form of a data set in online supplemental table 1). All patient data will be protected using institutional guidelines. This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the *International Conference on Harmonisation* – Good Clinical Practice, the *Human Research Act* and other locally relevant legal and regulatory requirements. Study data will be recorded using REDCap.

The results of this study will help guide this proposed new treatment, and therefore, wide dissemination of our findings is intended on both a national and international level. Peer-reviewed publications in international and regarded journals related to the subject and presentations at international meetings to important stakeholders will be sought. Preference will be given to open-access publishing.

Consent procedure

The investigators and research personnel will explain to each participant (or their caretaker) the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits, and any discomfort it may entail. Each participant (or their caretaker) will be informed that participation in the study is voluntary and that he or she may withdraw from the study at any time and that withdrawal of consent will not affect his or her subsequent medical assistance and treatment.

The participant (or their caretaker) will be informed that his or her medical records may be examined by authorised individuals other than their treating physician.

All participants (or their caretaker) for the study will be provided with a participant information sheet and a consent form describing the study and providing sufficient information for participants to make an informed decision about their participation in the study (online supplemental appendices 5 and 6). Patients (or caretakers) will be given at least 24 hours to decide whether to participate or not. However, patients can be included if they wish to give their consent before 24 hours. The formal consent of a participant, using the approved consent form, will be obtained before the participant is submitted to any study procedure (online supplemental appendix 5). In the case of a patient without discernment, the consent form could be signed by his/her representative (online supplemental appendix 6). The consent form will be signed and dated by the investigator or his/her designee at the same time as the participant signs. A copy of the signed informed consent will be given to the study participant. The consent form will be retained as part of the study records.

In case of emergency, if MMA embolisation can be performed directly following the surgery, as this would reduce the risk associated with undergoing a second anaesthesia for the embolisation sometime after the surgery, the patient could be recruited in emergency (online supplemental appendices 7 and 8). The anaesthesiologist involved in the care of the patient, but not involved in the project, will be consulted before the emergency inclusion of the patient in the study. The consent of the patient (online supplemental appendix 7) or of her/his legal representative (online supplemental file 8) will be requested a posteriori. If the patient or her/his legal representative refuses consent, the patient's data will not be included in the study.

In case of a consent withdrawal, a consent withdrawal declaration form will be signed by the patient (online supplemental appendix 9) or by their representative (online supplemental appendix 10).

Patients who decide not to participate in the study will be treated as per current standard of care.

Amendments

Substantial changes to the study setup and study organisation, the protocol and relevant study documents will be submitted to the Ethics Committee for approval before implementation. Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of human subjects may proceed without prior approval of the Ethics Committee. Such deviations shall be documented and reported to the Ethics Committee as soon as possible.

CONCLUSION

This multicentre randomised controlled trial offers an opportunity to provide definitive answers on whether MMA embolisation has clear clinical benefits for patients when used in addition to surgery. Such a benefit would be represented by a decreased recurrence of cSDH and therefore a reduced need for reintervention. The consequence of this benefit includes not only better outcomes but also reduced healthcare-related costs. The secondary objective of the study is to assess whether MMA embolisation by itself carries benefits for patients not surgically treated due to refusal or significant health-related contraindications. The aim of this second objective is to determine the effectiveness of MMA embolisation in stopping the progression of cSDH.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

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