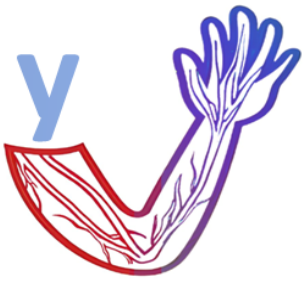
# ARMIES

# ARM IschaEmia Study



# Protocol: ARM IschaEmia Study (ARMIES)

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## Study summary

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|---|---|
| Full Title | Arm IschaEmia Study (ARMIES) |
| Short Title | ARMIES |
| Study Design | Multicentre, prospective service evaluation project |
| Study participants | Patients with upper limb acute ischaemia |
| Planned study period | Each site will be a minimum of 3 month recruitment period and a one month follow up period. |
| Planned study start date | **7th October 2024** |
| Planned study end date | **7th May 2025** |
| Study Objectives | **Primary Objective**<br>Compare treatment strategies and clinical outcomes for patients with acute upper limb ischaemia to published European Society of Vascular Surgery guidelines.<br>**Secondary Objectives**<br>Describe the incidence of acute upper limb ischaemia, the proportion of patients undergoing medical and surgical treatment, patient outcomes, and risk factors associated with these. |
| Study Outcome measures | **Primary outcomes:**<br>1. To identify the Incidence of acute upper limb ischaemia<br><br>**Secondary outcomes:**<br>1. To determine variations in practice in the management of acute upper limb ischaemia.<br>2. Identify the 30-day amputation rate<br>3. Identify the 30-day Major Adverse Cardiovascular Event rate<br>4. Identify risk factors for 30-day amputation and Major Adverse Cardiovascular Event rate<br>5. Identify complication rates, functional outcomes, re-intervention rates, length of hospital stay and impact on residential status. |

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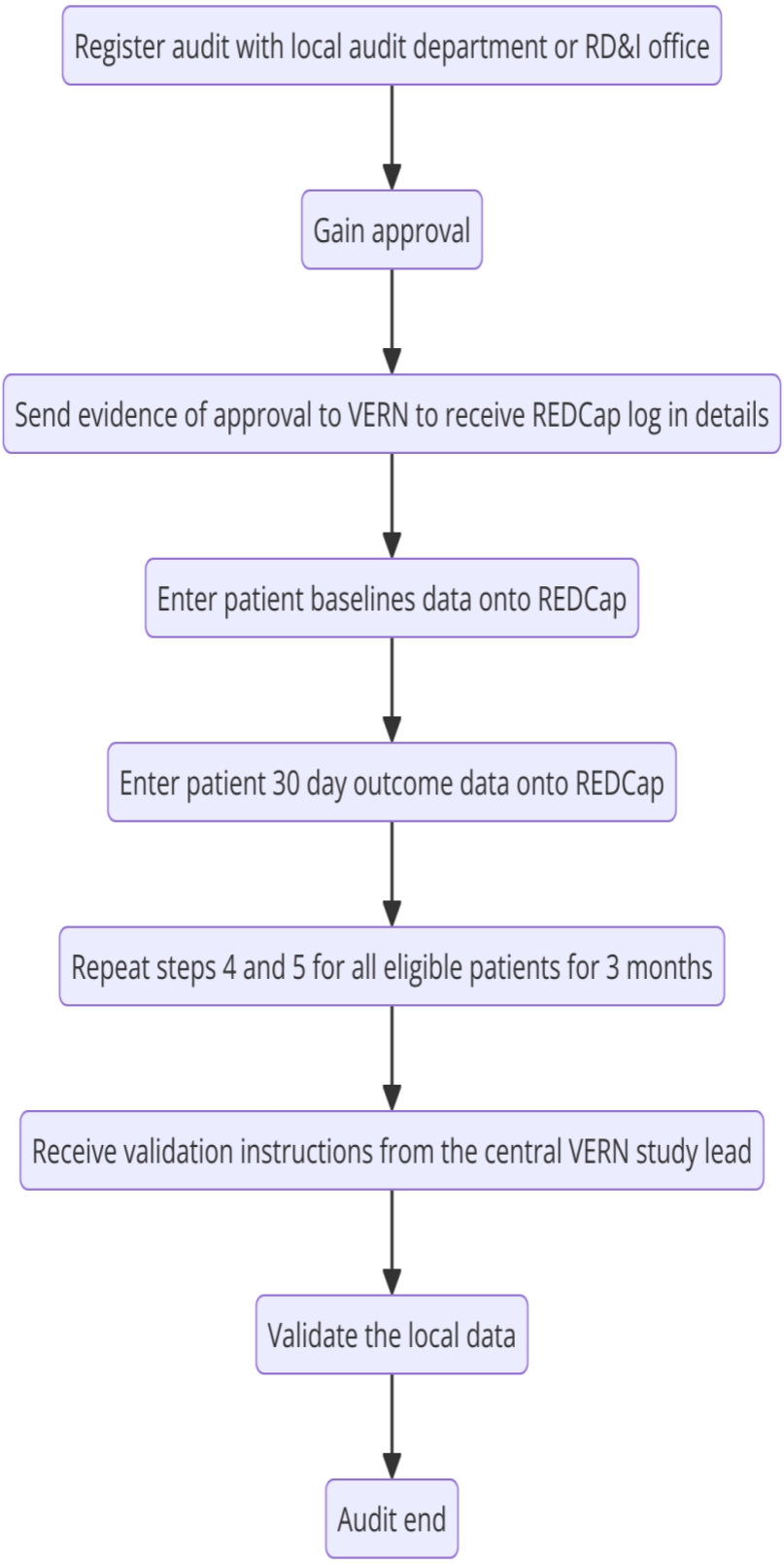
| **Coordinating Centre** | Northern Vascular Centre, Freeman Hospital Newcastle |
| **Number of subjects** | 50 |
| **Eligibility Criteria** | **Inclusion criteria:**<br>· Patients over 18 years of age<br>· Acute upper limb ischaemia[<br><br>**Exclusion criteria:**<br>· History of arteriovenous fistula in affected arm<br>· Connective tissue disease<br>· Traumatic/Iatrogenic cause of acute upper limb ischaemia<br>· Previous history of acute upper limb ischaemia |
| **Duration of data collection** | Each site will be a minimum of 3 month recruitment period and a one month follow up period. |

## Study flowchart



**Audit Protocol: Arm IschaEmia Study (ARMIES)**

## 1- Introduction

Acute upper limb ischaemia (AULI) is a serious vascular condition caused by the sudden interruption of arterial blood flow to the upper extremities. The Rutherford classification for acute limb ischaemia categorises the severity of ischaemia to guide treatment decisions: Category I (Viable) indicates no immediate threat, with normal motor and sensory functions; Category IIa (Marginally Threatened) signifies a salvageable limb with prompt treatment, presenting mild sensory loss but no muscle weakness; Category IIb (Immediately Threatened) requires urgent revascularisation due to severe pain, significant sensory loss, and mild to moderate muscle weakness with typically inaudible Doppler signals; and Category III (Irreversible) denotes irreversible damage with profound sensory loss, paralysis, and absent Doppler signals, often leading to major tissue loss or amputation (1) .

When paralysis and/or paraesthesia are present, revascularisation is required within 6 hours, and the conventional intervention for AULI is surgical intervention (2). Patients presenting with only pain and pallor, without paralysis or paraesthesia, may warrant urgent revascularisation; however, some may improve with medical management alone.(2).

To date, no randomised controlled trials have compared the treatment methods for patients with acute upper limb ischaemia (Rutherford IIa). Effective management of AULI is highly contingent upon assessing the ischemic severity and pinpointing the etiological factors at play. As per the European Society for Vascular Surgery (ESVS) 2020 Clinical Practice Guidelines, a conservative regimen involving anticoagulation is deemed sufficient for some patients, nevertheless these cases require ongoing surveillance to pre-empt any potential exacerbation of their condition (3). The latency of ischemic symptomatology and elevated serum lactate dehydrogenase levels correlate with an increased risk for functional aftermaths, which include enduring pain and restricted mobility of the impacted limb (4). Delays in revascularisation are associated with a heightened rate of neurological sequelae but do not significantly impact limb salvage rates if the ischemic duration surpasses 12 hours (5).

### Study rationale

There is currently a lack of evidence to guide management in AULI, particularly Rutherford IIa, on utilising either medical therapy alone or with surgical intervention. To address this gap in knowledge, this multicentre service evaluation project ‘ARMIES’ has been developed to evaluate the current treatment strategies and clinical outcomes for patients with acute limb ischaemia against the published European Society of Vascular Surgery guidelines. Through collection and analysis of outcome data, ARMIES will understand how well centres adhere to guidelines and compare UK data to published National databases (6).

### Study aim

To evaluate the current treatment strategies and clinical outcomes for patients with acute limb ischaemia against the published European Society of Vascular Surgery guidelines.

### Primary Objective

Compare treatment strategies and clinical outcomes for patients with AULI to published European Society of Vascular Surgery guidelines.

### Secondary Objectives

Describe the incidence of AULI, the proportion of patients undergoing medical and surgical treatment, patient outcomes, and risk factors associated with these.

**Study Outcome measures**

**Primary outcomes:**

To identify the:

- Incidence of acute upper limb ischaemia
- Proportion treated medically vs surgically.
- Proportion of reintervention rates.

**Secondary outcomes:**

1. To determine variations in practice in the management of acute upper limb ischaemia.
2. Identify the 30-day amputation rate
3. Identify the 30-day Major Adverse Cardiovascular Event rate (MACE)
4. Identify risk factors for 30-day amputation and Major Adverse Cardiovascular Event rate
5. Identify complication rates, functional outcomes, re-intervention rates, length of hospital stay and impact on residential status.

**Study Design**

**Overview**

ARMIES is a multicentre study of practice disseminated via the Vascular and Endovascular Research Network (VERN). VERN is a trainee-led national research collaborative that is run by, and engages with, research-active vascular trainees and allied health professionals, and has expertise in running national and international study of practice.

**Setting**

Hospitals providing emergency acute upper limb arterial surgery in the UK and abroad, recruited via VERN. Based on previous VERN studies at least 25 units are expected to be enrolled. ARMIES will also capture how non-UK centres practice aligns to UK practice and published data.

**Target population**]

Adults over the age of 18 receiving emergency surgical, endovascular, or medical therapy for AULI.

**Eligibility criteria**

The multicentre service evaluation project will capture data on consecutive patients admitted with AULI. Any patients over the age of 18 with AULI affecting either arm will be eligible if they meet the specified criteria below. Eligible patients will be identified by screening data available to the clinical team; patients will not be approached/contacted during any part of ARMIES, and there should be no change to any patient care during the course of the study. In patients with bilateral AULI the worst affected limb will be classified as the primary side for the study.

**The following criteria should be used to identify patients are eligible to be enrolled for data capture:**

**Inclusion criteria:**

- Patients over 18 years of age
- Acute upper limb ischaemia[

**Exclusion criteria:**

- History of arteriovenous fistula in affected arm
- Connective tissue disease
- Traumatic/Iatrogenic cause of acute upper limb ischaemia
- Previous history of acute upper limb ischaemia

**Interventions**

The study is observational and low risk. There are no additional interventions and only routinely collected data will be used. Decisions regarding medical management or surgical intervention will be at the discretion of the clinical team.

**Registration**

This audit will be open to any vascular surgery centre managing upper limb acute ischaemia. Each collaborating site must prospectively register their intention to participate in ARMIES with VERN, via the ARMIES registration form. Evidence of Research, Design and Innovation Office or Audit Department approval at each site must be shared with VERN prior to data collection. Obtaining local approval to participate in ARMIES will be the responsibility of the local project lead.

The local study team will be responsible for the identification and recruitment of potential participants as per the eligibility criteria. Queries with regards to participant eligibility will be dealt with by the local audit lead or, in case of non-resolution, referred to the VERN team.

**Patient Pathway and Identification**

Once a centre is open to ARMIES, data from consecutive patients presenting with AULI meeting the eligibility criteria will be collected prospectively. Data will be captured for each participant until 30 days following intervention (with a potential to extend to one year – see below).

Local Information Technology (IT) systems, theatre lists and in-patient lists will be used to screen for eligible patients. In the event of a patient already enrolled into ARMIES having a further episode of AULI this will be recorded as recurrence, however they will not be entered as a new record.

**Data Collection**

**Patient Entry**

Once eligibility is confirmed, the baseline data collection should be completed. When the data are uploaded onto the ARMIES REDCap database, a unique REDCap identifier will be allocated to the patient. This unique study number will be used in all correspondence between the ARMIES study office and the site. Linkage between the REDCap ID and patient should be maintained securely at the hospital site.

Key demographic data, baseline variables and medication data should be collected as early as possible. The initial treatment plan and times of decision for any changes in treatment will be recorded alongside rationale i.e. limb deterioration, limb failure to improve, reocclusion.

Follow up data points will be collected up until 30 days following intervention. In the case of MACE development, further details will be required regarding the extent of MACE and subsequent patient

outcomes. Data will be obtained using patient notes and electronic records; pre-operative assessment, clinic letters, theatre IT systems, discharge summary and A&E and GP records (where available). No changes to normal follow up will be made and the patient will not be contacted.

**Clinical outcomes**

***Data collected by clinical team at index admission and 30-day follow up:***

1. Basic patient demographics
2. Patient comorbidities (malignancy, atrial fibrillation, arterial embolization, peripheral aneurysm, stroke, aortic dissection, prior revascularization to affected limb, diabetes, renal failure, myocardial infarction, ischaemic heart disease, hypertension)
3. Patient medications on admission (statin, antiplatelet, anticoagulant) including recent stop, and admission INR if on warfarin
4. Rutherford Ischaemia Class. Severity of sensory and motor deficit.
5. Aetiology of acute limb ischaemia (thrombosis, embolus, thrombosed aneurysm, thrombophilia, anatomical variation e.g., TOS)
6. Concomitant embolic focus if seen (carotid, coronary, vertebral, visceral, renal, lower limb, other)
7. Level of index occlusion (subclavian, brachial, radial, ulnar)
8. Time to presentation
9. Primary treatment option (medical, surgical, endovascular)
10. Change to treatment option including time and date, and rationale for change i.e. limb deterioration, failure to improve
11. Primary or delayed fasciotomy
12. Intra-operative completion angiogram
13. Palpable radial and ulnar pulse at completion of intervention and at discharge
14. Residual sensory or motor deficit on discharge
15. 30-day mortality incidence
16. 30-day MACE
17. 30-day major and minor amputation rate
18. (If applicable – see below) 1-year mortality, reintervention, MACE and amputation rates
19. Surveillance protocol
20. Anticoagulation protocol
21. Residential status on admission and discharge

**Site level data**

On enrolment to ARMIES, each centre will be asked to complete a baseline unit survey. This will collect data on individual centres' clinical care pathways and policies surrounding AULI.

**Recruitment Projection**

Based on this estimation, with 25 centres taking part in ARMIES, it is anticipated that data on up to 50 patients may be captured over a 6 month period. We will however, be happy to exceed this number in terms of both the number of centres and the number of patients.

**Estimated milestones are:**
Study Sign up: 7th October 2024
First recruitment: 7th November 2024
Last recruitment: 7th April 2025
Last follow up data point (30-day outcomes): 7th May 2025

**Statistical Considerations**

The statistical analysis of this study will be undertaken by our research team based within the Northern Vascular Centre, Freeman Hospital, Newcastle upon Tyne, and Norfolk and Norwich University Hospital, Norwich. The report of the multicentre service evaluation project will be prepared in accordance with the guidelines as set by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for observational studies.

Continuous variables will be summarised with means and standard deviations; frequencies and percentages will be used for categorical variables. Univariate and multivariate analyses will be assessed by appropriate statistical techniques. Multilevel-logistic regression models will be used to allow for clustering at a centre or a country level. A p-value of $<0.05$ will be considered significant for all statistical methods used and the analysis will be completed using appropriate statistical software. The performance of individual hospitals will not be disclosed and all subgroup analysis will include large patient cohorts to protect patient anonymity. No surgeon- or hospital-specific comparisons will be performed in the final dataset.

**Data Handling and Record Keeping**

**Data Management**

**Data will be collected at the following times:**

- At the time of presentation with AULI
- At 30 days following intervention.

Data will be entered directly onto the ARMIES REDCap database by study collaborators at participating hospitals sites. REDCap is a secure, web-based software platform designed to support data capture of single and multi-site studies (8-9).
Source data will be used and uploaded electronically using an internationally recognised secure web application for building and managing online databases (REDCap). It is encouraged that data will be

uploaded directly to REDCap as close to the time of presentation as possible. Paper data collection sheets will be provided to centres to facilitate data capture when direct upload to REDCap is not possible at the time of intervention. No patient identifiable data will be transferred to REDCap.
Site study collaborators will be provided with a paper copy of the electronic data collection sheet to facilitate data collection. If this is used, they should then transfer data from the paper data collection sheet to the online ARMIES database located at REDCap. ARMIES data management staff will check all incoming data for completeness, data consistency and compliance with the protocol. If discrepancies or missing data are identified, the ARMIES data management staff will raise queries with the study team at the participating hospital.
Data validation comprises confirmation of case ascertainment and data accuracy. At the close of the data capture timeframe, centres will be asked to review theatre/interventional radiology logs to ensure that all patients undergoing AULI intervention during the data-collection time frame were entered. Any patients not included will be added retrospectively; it is appreciated that not all data may be available retrospectively, but the ARMIES team will account for this during analysis and dissemination.

**Missing Data**

The online database has been designed to allow sites to securely access an individual patient's data throughout the study period. This means that any missing or erroneous data can be altered by the local investigators whilst the data collection period is ongoing. In order to maximise data completion and emphasise its importance to collaborators, participating centres with > 5% missing data in mandatory fields (i.e. < 95% data completeness) will be excluded from the study, as is standard within international collaborative studies (10).

**Data Security and Data Protection**

The security of the study database system is governed by the policies of Newcastle Hospitals NHS Foundation Trust. The ARMIES database will be hosted on the University's REDCap system managed and maintained by Newcastle University.
Data management and data security will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. The study will be conducted at collaborating sites in accordance with the current data protection requirements. Data will be acquired and stored on the REDCap platform. Access to data will be restricted, each individual collaborator entering data for ARMIES will have their own username and password. Each participant will be allocated a unique study number at entry. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual will be identifiable.

**Confidentiality**

Patient identifiable information will not be collected in this study. All participant data held at the Northern Vascular Centre, Freeman Hospital, Newcastle Hospitals NHS Foundation Trust will be anonymised. All data collected about participants will be identified using only a unique ARMIES study number (REDCap ID). This number will be automatically allocated via REDCap once a new patient record is created in the ARMIES database.
Any correspondence between the ARMIES study office and hospital sites will use the ARMIES study number only.

The linkage between REDCap study ID and participants will be maintained in strict confidence at participating sites. This data will not be submitted to the ARMIES study office and will not be sent outside of the participating site. A template document will be sent to centres on enrolment to be overseen by the local lead, who will be responsible for ensuring this file is only stored on-site, and is done so securely.
Confidentiality of all participants' data will be maintained and there will be no disclosure of information by which participants may be identified to any third party other than those directly involved in the treatment of the participant. The participants will not be identifiable with regards to any future publications relating to this study.

**Ethical Approval**

Every participating centre will register the study locally prior to data collection (study and service provision registration at all NHS sites involved). This multicentre service evaluation project does not require approval from the NHS Research Committee as per guidance by the healthcare Research Authority (see appendix 1). Centres outside of the United Kingdom should comply with local regulations. The study is required to be registered with each participating centre prospectively, prior to data collection. This is typically with the service evaluation department, or 'Research and Development' department. Participating centres outside of the UK must comply with local regulations prior to commencement. The study is open to all centres that undertake AULI management. In the case of UK vascular units, often they comprise a Hub and Spoke type model. A registered Hub site may be able to undertake data collection for the Spoke sites without registering the spoke site separately.

**Service Evaluation Administration**

The service evaluation has been developed by a study management team with expertise in AULI surgery. The project will be under the auspices of the Project Lead (PL). The project will be overseen by a Study Management Group (SMG). This SMG will be chaired by the PL.

**Local Study Teams**

Each centre will require the support of a named supervising consultant/attending (or equivalent), who will act as guarantor of all activity undertaken at that centre, and a data collection team.
Each participating centre will be responsible for identifying a Site Lead and a data collection team. The site lead should be at least of a consultant level or equivalent. Where feasible the use of trainee collaboratives will be encouraged to aid in the delivery of this study. The role of Site Lead is to:

- Promote the study at site and facilitate delivery at site
- Liaise with the SMG
- Ensure that mechanisms for upload of data relating to eligible participants is in place
- Ensure appropriate local staff resources are maintained (cover provided for absence) to deliver the service evaluation.
- Ensure local approvals are in place.

The local team will be responsible for pseudonymised data collection and data validation. Therefore national data opt out preferences will be applied locally. This team will comprise a

maximum of a supervising consultant/attending and a further 6 individuals, and can include medical trainees or allied healthcare professionals.

**Publication Policy**

The PL will coordinate dissemination of data from this project. All publications using data from this study to undertake original analyses will be submitted to the SMG for review before release. The success of the study depends on a large number of clinicians. For this reason, credit for the results will not be given to the committees or central organisers, but to all who have collaborated and participated in the study. Acknowledgement will include all local co-ordinators and collaborators, members of the study committees, the SMG and administrative staff. Authorship at the head of the primary results paper will be cited as a collaborative group to avoid giving undue prominence to any individual. All contributors to the study will be listed at the end of the report, with their contribution to the project identified. Those responsible for other publications reporting specific aspects of the study may wish to utilise a different authorship model, such as "[name], [name] and [name] on behalf of the collaborative Group ''. Decisions about authorship of additional papers will be discussed and agreed by the Project lead and the SMG.

To qualify for PubMed-citable collaborative co-authorship individuals must have either;

- Had a significant role in the set up and management of the study, including service evaluation department registration, creation of a data collection team and engagement with VERN to ensure timely upload of data (with validation) and completion of the questionnaire

OR

- Capturing sufficient data to warrant authorship – this would be the equivalent of collecting baseline and follow up data, although it is appreciated individuals may participate in only baseline data collection or only follow up data capture. Data collection is expected to be complete (>95% variables completed), and submitted in a timely manner

OR

- (For consultants/attendings) provided oversight and support as detailed in the ''Centre Eligibility and Team Roles" section.

The local lead at each centre will be responsible for ensuring that the ARMIES Management Group have the names and contact details of all collaborators who qualify for collaborative co-authorship at their centre. All collaborators will be given the opportunity to review draft paper(s) prior to submission. Whilst the ARMIES team appreciates the importance of this step, the team are also keen to ensure this stage does not add to significant delays in submission. All collaborators should inform the team of any changes in email addresses, and ensure their emails are checked regularly, as this stage will deliberately be kept short. Unless there are major issues or questions identified, collaborators will be given a single opportunity to comment on the paper before it's returned to the writing group for further review within 72 hours. The writing group will make a final decision regarding the comments and edits made during this process.

Plain language summaries will be created and distributed to national amputation charities and key stakeholders.

**Dissemination of Research Findings**

The results of this study will be submitted for publication in peer reviewed scientific journals, given the international nature of this study it is anticipated that this will be reflected in the journal selected. Results of the study will also be presented at meetings both national and international, according to the contributing nations. The findings of this study may be used to inform the design of further studies into AULI.

**Finance and Funding**

This study is not funded. The project will be coordinated by The Northern Vascular Unit, Freeman Hospital, Newcastle Hospitals NHS Foundation Trust and the Norfolk & Norwich University Hospital NHS Trust, and thus the burden of the cost will lie within the UK. Participating centres will not bear any costs for being part of this service evaluation project. Similarly, no financial reimbursement will be made to units or investigators for their involvement.

**Table 1 – A survey of routine practice**

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|---|---|
| Unit name | |
| Local lead consultant/attending | |
| Local lead consultant/attending email | |
| Team member 1 | |
| Team member 2 | |
| Team member 3 | |
| Team member 4 | |
| Research/Ethical/Research and Development/Audit Department Contact Name | |
| Research/Ethical/Research and Development/Audit Department Contact email address | |
| Date of approval | dd/mm/yyyy |
| Please fill in the ARMIES survey (if not completed prior to study registration) | Link to the survey: https://forms.gle/6393CFLM9sR1psvu5 |

## Sign up form

## ARMIES Registration form

Please complete the form below to register for the ARMIEs audit with VERN. Following registration you will receive access to REDCap for data entry.

When providing contact emails, please use work (i.e. nhs.net) or university based emails, please do not use personal emails (gmail, hotmail, etc).

* Indicates required question
1.Name of hospital, city and country
2.Name of Lead Clinician (consultant/attending)
3.Contact email for Lead Clinician (Please provide ORCID ID if available)
4.Please provide name, role and contact email of a team member responsible for patient identification, recruitment and data entry. (Please provide ORCID ID if available)
5.Please provide name, role and contact email of a team member responsible for patient identification, recruitment and data entry. (Please provide ORCID ID if available)
6.Please provide name, role and contact email of a team member responsible for patient identification, recruitment and data entry. (Please provide ORCID ID if available)
7.Please provide name, role and contact email of a team member responsible for patient identification, recruitment and data entry. (Please provide ORCID ID if available)
8. Please provide the name, role and contact email of a team member responsible for patient identification, recruitment and data entry. (Please provide ORCID ID if available)
9. Please provide date of local governance/audit approval
10. Please provide the name of the responsible/nominated local governance/audit officer.
11. Please provide a contact email of the responsible/nominated local governance/audit officer.
12.Please provide evidence of local governance/audit approval

**References**

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