The POPPY study site information leaflet

Patient reported Outcomes, postoperative Pain and Pain relief in daY case surgery

The POPPY study is the 4th RAFT (Research and Audit Federation of Trainees) national research project. This leaflet aims to give sites a brief overview of the study objectives, processes and what taking part will entail. The full protocol for the POPPY study can be found on our website.

The POPPY study will pilot in July 2023 with the main portion launching in January 2024. Currently we are looking for sites to register an interest in joining the study. The POPPY study is NIHR portfolio adopted and affiliated with the NIHR Associate PI Scheme.

For updates on the POPPY study have a look at our website, follow us on twitter and join up to the RAFT mailing list.

If you have any questions after reading this leaflet please get in touch via e-mail: plh-tr.poppystudy.raft@nhs.net

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Study overview

The POPPY study is a national anaesthetic trainee led prospective multi-centre mixed methods observational cohort study investigating reported outcomes in quality of recovery, postoperative pain and pain relief in adults undergoing day case surgery in the UK. It will include all adult patients (18 years or older on the day of surgery) who are having day case surgery (excluding overnight or 23 hour stay) that requires an anaesthetist to be present for the case. The study will not include paediatric cases, diagnostic procedures (e.g. radiology, endoscopy), minimally invasive (e.g. day case cardiology procedures), obstetric procedures and ophthalmic procedures.

Study sites will be responsible for patient recruitment, consenting and data collection on the day of surgery. All post-operative follow up for the study will be via text or email using a data secure online system called NewcastlePROMS (https://newcastleproms.co.uk) which is already in use in NHS hospitals for patient follow up. At the end of quantitative data collection a small number of patients will be selected and invited to take part in the qualitative portion of the study.

The primary objectives are:
- to measure the quality of recovery in the UK day case surgical population during the first postoperative week
- to measure the prevalence of persistent post surgical pain (PPSP) and persistent postoperative opioid use (PPOU) in the UK day case surgical population

Secondary objectives include:
- identify the characteristics that are associated with poor quality of recovery and the development of PPSP and PPOU
- describe the prevalence of acute pain and analgesia use during the first postoperative week
- investigate the differences in quality of life between patients with and without PPSP
- describe the patient reported acceptability of SMS prompted long term follow-up in observational studies in anaesthesia

The aims of the qualitative part of the study are to explore the patient experience of day case surgery, acute recovery, longer term recovery and opioid use in patients experiencing PPSP.

The importance of investigating quality of recovery and long term pain outcomes in the UK day case population

Around seventy percent of all surgical procedures in the UK are day case procedures[1] and approximately six million day-case procedures are performed each year[2]. Although some day case units carry out next day follow up of day case patients this is not universal and increased knowledge of quality of recovery and PPSP and PPOU in the UK day case population is needed. The prevention of chronic pain has been identified as a top priority for anaesthetic research[3]. There is growing evidence that patients undergoing day case surgery can develop long term complications including PPSP and PPOU. Large studies outside the UK have shown that PPSP and PPOU are significant issues in the day case population however data in the UK is lacking. Extrapolation from studies from the USA suggests that between 24,000 - 104,000 of day case and inpatient surgical patients in the UK develop PPOU each year and 114 - 6240 of these patients will develop an opioid misuse disorder[4].

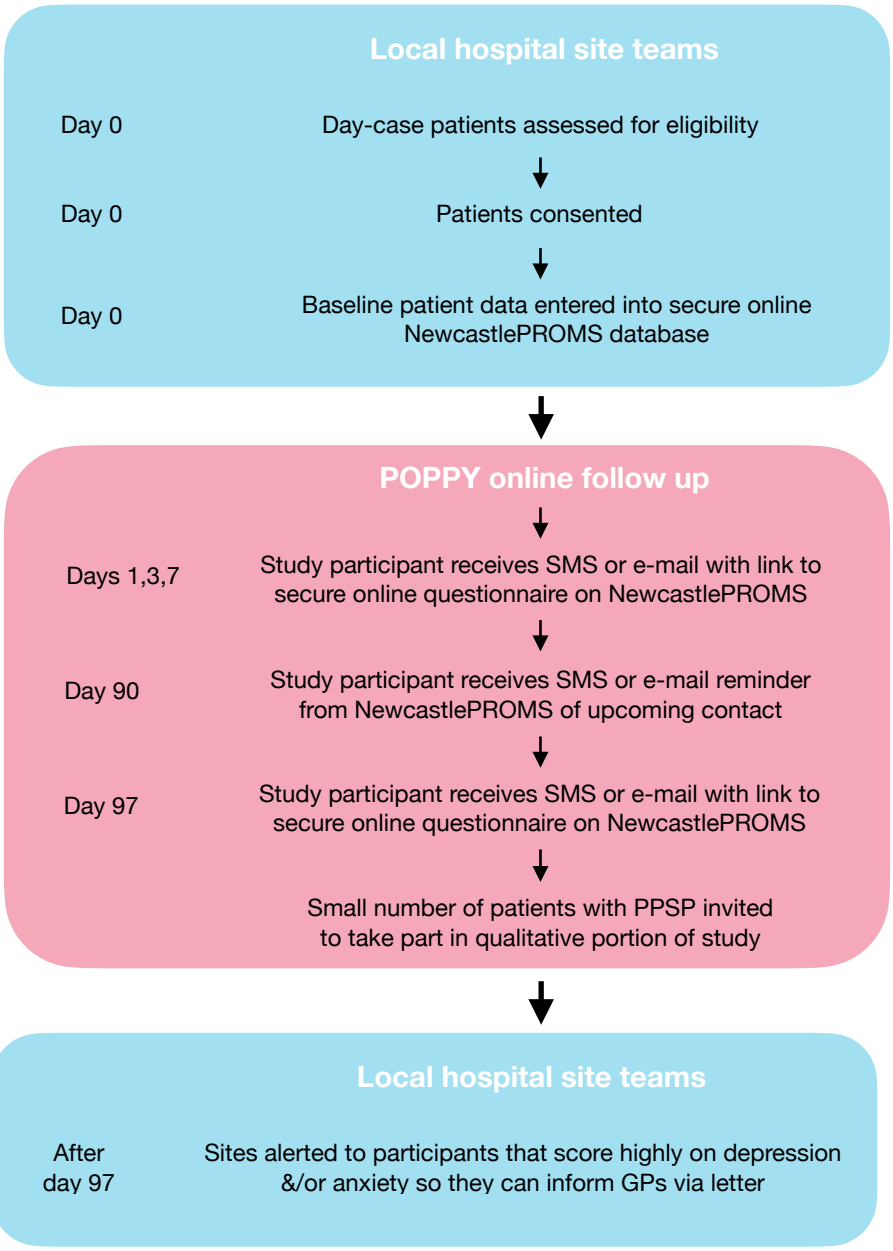
How this topic was chosen as the 4th RAFT national study

RAFT is a UK wide collaborative network of Trainee Research Networks (TRNs) run by trainee anaesthetists interested in research and quality improvement. TRNs are the heart and soul of RAFT, they link hospitals and work together to identify and address important research questions and areas for quality improvement. Every 2 years (bar the pandemic) RAFT aims to conduct a national study with the topic being chosen by RAFT members through a competitive process. In 2021 the idea of the POPPY study was put forward by trainees from SWARM (South West Anaesthesia Research Matrix) and against stiff competition it became the 4th RAFT project.

Site responsibilities and study timeline

During the 5 day study period local POPPY sites will be responsible for:

- Assessing eligibility of day case patients
- Asking usual care providers (e.g. anaesthetist or surgeon looking after the patient) to make their patients aware of the study
- Consenting patients
- Collecting baseline patient data on the day of surgery and inputing this on the secure online POPPY NewcastlePROMS online platform



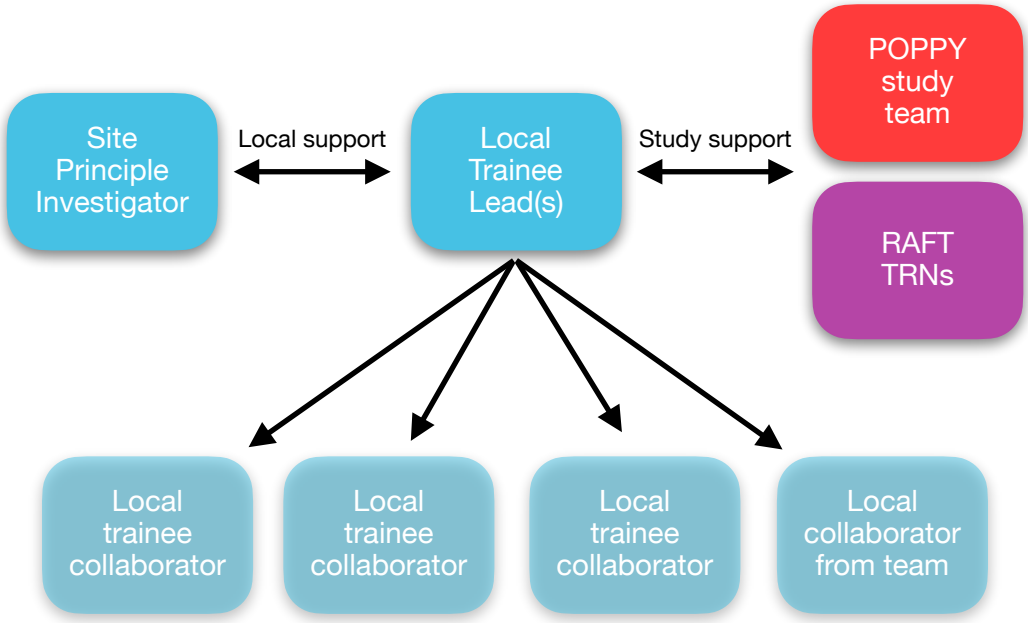
All post-operative follow up including the qualitative portion of the study will be managed by the central POPPY study team. Patients will be followed up postoperatively on days 1, 3, 7 & 97 via SMS with a link to online data secure questionnaires. At each point of contact all study participants will be given the option to withdraw from the study. On day 97 participants with ongoing pain at the site of surgery are asked to complete surveys on depression and anxiety. If participants score highly on these surveys an alert is sent to the local research team so that they can inform the participant's GP.

All members of local teams will need to have an up to date GCP certificate. As with previous RAFT projects we advice that teams are made up of several local collaborators working together over the study period to ensure that all eligible patients are offered the opportunity to be involved with POPPY.

To ensure success the local site team should include:

- Principle Investigator who will express site interest and provide relevant details for the study IRAS form and be a port of call for hospital specific support to the local team.
- POPPY Trainee Site Lead(s) will lead the setting up and running of the POPPY study within their hospital.
- Local POPPY Collaborators will be key in the delivery of the POPPY study during the study period by screening, recruiting and consenting patients plus collecting baseline patient data.

Local site teams will be supported by the POPPY study team, regional trainee research networks and the RAFT committee.



Certificates of involvement will be provided to all site leads and local collaborators as evidence of project involvement and their role. They will also be included in the POPPY study collaborator list for all POPPY publications and presentations.

The POPPY study online data platform

Newcastle PROMs (https://newcastleproms.co.uk/) is a secure online system already used within some NHS hospitals for patient follow up using SMS delivered surveys. A major advantage is its bespoke researcher and participant facing system. This has been carefully designed in collaboration with the central study team and our patient and public involvement and engagement group. The POPPY online platform on Newcastle PROMs will include a section for local researchers to register their site and input baseline data and automatic SMS follow-up for participants after surgery. It is able to automatically send safety alerts to be sent if participants have scored highly on depression &/or anxiety surveys with signposting advice. Alerts will also be sent to the local research teams so that GPs can be informed. Newcastle PROMs can be used on all electronic devices with access to the internet which means that researchers can collect baseline data on computers, tablet devices or mobile phones.

Is SMS/e-mail follow up secure and will it work? Newcastle PROMs meets all necessary data protection and security requirements mandated for management of study data in the UK health service. NewcastlePROMS has already been used successfully for postoperative feedback in multiple UK NHS hospitals. In the UK >95% of people under 55 years of age have access to a smart phone with 90% of people between 55-64 years and 69% of people >65 years. Mobile phone ownership is growing in those over 65 years by around 5% per year. We also anticipate that those without a smartphone may well have access to one e.g. spouse or family members. ONS data in 2020 showed that 96% of households in Great Britain have access to the internet. If we are able to demonstrate SMS/e-mail follow up efficacy with POPPY this will have important implications for future research.

Why POPPY is important to patients

We believe that by addressing our study objectives we will be able to provide a clearer picture on patients' experience of recovery from day surgery, rates of persistent post surgical pain and persistent postoperative opiate use in the UK. We also hope to describe associated risk and protective factors for poor post surgical outcomes following day surgery. We have involved patient representatives in all stages of planning POPPY to ensure that the research aims are relevant to our patients. We will continue to have this invaluable patient and public involvement and engagement group (PPIE) input throughout the study.

Why POPPY is important to developing anaesthetists

The idea for POPPY was developed by anaesthetic trainees in the South West of England and chosen to become the 4th RAFT project by anaesthetic trainees across the UK. Its development and the day to day running is very much lead by trainees, with oversight and advice from experienced researchers. POPPY is a great opportunity for all developing anaesthetists in the UK to get involved in a trainee research network (TRN) led national research project and develop their own research, leadership and team working skills. The 2021 RCoA curriculum refers to TRN activity in all stages stages of the curriculum and so being involved with POPPY will support trainees working towards a CCT or CESR in anaesthesia.

RCoA curriculum TRN personal activity evidence for research and managing data:

- **Stage 1:** "*awareness of local Trainee Research Network activity (TRN)*"
- **Stage 2:** "*participation in Trainee Research Network activities*"
- **Stage 3:** "*active involvement with local Trainee Research Network (TRN) such as local lead for a TRN study*"

Is the POPPY study affiliated with the NIHR Associate PI Scheme?

Yes! The POPPY study is affiliated with the NIHR Associate PI Scheme (more information on the is scheme can be found here). This will allow those who want to take a leadership role locally at sites to get a formal research qualification.

Who can become involved with POPPY

We invite anybody with an interest in research to get involved with POPPY. Trainees, locally employed and SAS anaesthetists of comparable experience to take key roles within POPPY teams. Having a diverse group of people involved in projects is important to ensure we can share learning and make our research more impactful. So we also welcome all anaesthetists, ODPs, nurses working in theatres or perioperative care services, research nurses and students to be involved too!

How to get involved with POPPY

We are open for sites to register an interest in joining the study. First check our website to see our regularly updated list of POPPY sites to check if your hospital has already signed up. If your hospital is not on the list please get in touch with the information below.

How to register your hospital with POPPY

If you are a site PI or have identified a PI for your site and you would like to join the POPPY study please e-mail the following details to **plh-tr.poppystudy.raft@nhs.net**:

- E-mail subject heading: **POPPY SITE REGISTRATION**
- In the e-mail include your:
  - **Organisation name**
  - **Organisation full address** (including postcode and country)
  - **Principle Investigator details:**
    - **Full name**
    - **E-mail address**
    - **Medical qualification (e.g. MBBS)**
  - **R&D contact**

Where there is no Principal Investigator for the site a Local Collaborator can be put down. This is normally the head of your anaesthetic department or a permanent member of staff within the department with whom the Chief Investigator has negotiated access to the site.

References

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