PROMPT: PROcedural sedation vs Methoxyflurane a Prospective co-horT Study.

ACTRN12623001127695

Status	RECRUITING
Phase	Phase 3
Sponsor	South Western Sydney Local Health District Human Research Ethics Committee
Enrollment	150 participants

Plain Language Summary

The PROMPT Study is comparing two approaches to pain relief and sedation for patients undergoing procedures in the interventional radiology department — procedures like biopsies, drain insertions, or catheter placements that can cause discomfort. One approach uses traditional intravenous medications (midazolam and fentanyl) given by the medical team. The other approach uses methoxyflurane (a pain-relieving inhaler, brand name Penthrox), which the patient controls themselves by inhaling as needed.

The key question is whether patient-controlled inhaled pain relief is as effective and safe as team-administered intravenous sedation, and whether it leads to a better experience for patients. Self-controlled pain relief may reduce the risk of over- or under-dosing and may give patients more comfort and control during procedures.

You may be eligible if you are over 18, are awake and able to consent, need more than just local anaesthetic for a procedure at Liverpool Hospital's Interventional Radiology department, and your procedure is expected to take less than two hours. People with allergies to these medications, kidney or liver problems, pregnancy, or who require general anaesthesia are not eligible. This study could help make minimally invasive procedures more comfortable and patient-centred.

Key Eligibility Criteria

Inclusion (6)

- Patients requiring periprocedural analgesia or sedation above local anaesthesia alone for procedures in the Liverpool Hospital Interventional Radiology Department will be offered participation in the study. Participants must be over 18 years of age and have capacity to provide consent. Written informed voluntary consent will be obtained. Patients must be hemodynamically stable. Expected procedure time must be under 2 hours.
- able to consent for procedure and participation in research
- patients requiring periprocedural analgesia or sedation above local anaesthesia alone
- hemodynamically stable
- expected procedure time <2h

... and 1 more (see full listing online)

Exclusion (9)

- The research project will be discussed with the patients at the time of consent. It will be clearly explained that they may opt out of the study or deny/withdraw consent at any stage. Patients unable to provide informed, voluntary, competent consent will be excluded. Similarly, if a sufficient understanding or communication cannot be established, including NESB/CALD, the patient will need to be excluded from the study and included in the discussion/exclusions analysis.
- Any patient with allergy or prior adverse reaction to methoxyflurane, midazolam or fentanyl will be excluded from the study. Patients requiring general anaesthesia or formal support by anaesthetist (e.g. needing intubation) will also be excluded.
- Patients with impaired renal function (eGFR<50) or liver dysfunction will be excluded due to the random possibility of receiving methoxyflurane as per standard of care for the safe administration of methoxyflurane based on the Australia Medical Handbook, Liverpool Hospital protocol and the Australian Therapeutic Goods Administration.
- renal impairment (eGFR<50)

- liver dysfunction

... and 4 more (see full listing online)

Locations (1 total)

Liverpool Hospital - Liverpool, NSW, Australia