IMPOSTER TRIAL

***I**nter**M**ittent **P**neumatic C**O**mpression Devices vs **S**tandard Therapy for the prevention of Venous **T**hrombo-**E**mbolic events: A **r**andomised clinical trial in patients undergoing surgery.*

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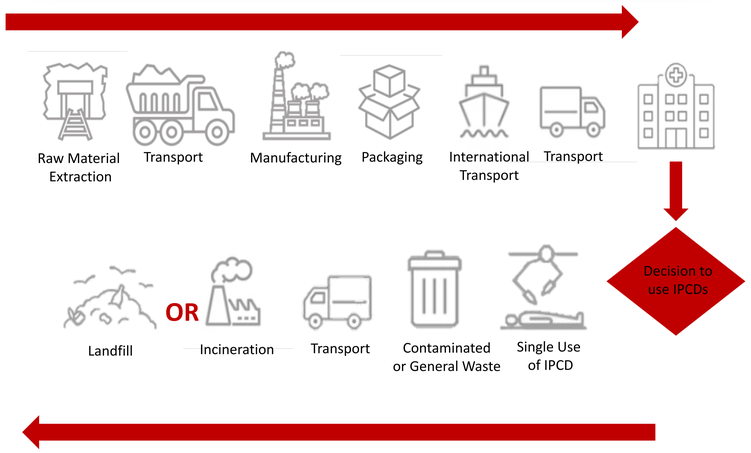
PROPOSAL

A multi-site, two-armed prospective, single-blinded, randomised controlled non-inferiority trial in patients undergoing major surgery examining the addition of IPCDs to standard prophylaxis for prevention of VTE.

A non-inferiority outcome will translate into significant cost-savings to the health care system, as well as reduce in-hospital plastic waste. A superiority outcome will result in improved perioperative care for patients.



VTE: venous thromboembolism

IPCD: intermittent pneumatic compression devices

GCS: graduated compression stockings

LMWH: low molecular weight heparin

BACKGROUND

There is a paucity of high-quality evidence to guide what is the best and most appropriate prophylaxis for patients admitted to hospital having major surgery. The 2009 National Health and Medical Research Council (NHMRC) guidelines, now rescinded and not replaced, stated there is a lack of available evidence in this area which necessarily limits the scope of evidence-based recommendations.

Our meta-analysis identified no study directly assessing VTE rates in patients given heparin and stockings compared to heparin, stockings and compression devices. We found compression devices were superior to placebo but not to other forms of prophylaxis.

Without an evidence base to inform current practice, surgeons often opt to use every method at their disposal. A surgeon survey in 2019 (n=214) found 92% of surgeons routinely use all three modalities. Over 40% expressed interest in a trial determining an optimal prophylactic approach, agreeing it is wasteful for patients to receive three forms if two will suffice.

Estimated Annual Impacts

- 200,000 IPCDs are used for major surgery across NSW hospitals annually, a cost saving of 22 million dollars
- $4 million in acquisition costs across NSW
- 20,000 hours of extra nursing time fitting/removing and monitoring patients with IPCDs across NSW
- 180 kg of packaging and 42200 kg of used IPCDs for disposal in landfill or incineration.

This study will be the first to assess optimal prophylaxis for prevention of VTE

SAMPLE SIZE

A sample size of 2814 (3120 to allow for 10% loss to follow up) is based on 90% power and an event rate of 2.5% and a non-inferiority margin of 1.5%.

SUMMARY

P: Adult patients undergoing major surgery at moderate & high risk of VTE.

I: LMWH and GCS alone

C: LMWH and both GCS and IPCDs

O: VTE incidence. Secondary outcomes are patient QoL, sleep quality, mortality, Clavin-Dindo classification, safety, & costs

T: 30 day and 90 day follow up

- Environmental impact
- Unnecessary intervention
- Wasted resources
- Increased potential for non VTE adverse events

SUPPORT

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