

Topical Nifedipine for Post Haemorrhoidectomy Pain Relief: A Randomised, Prospective, Double-Blind Placebo Trial Protocol

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Background

Haemorrhoidectomy is a common surgical procedure carried out by general and colorectal surgeons worldwide. Pain following haemorrhoidectomy is universal and problematic and thought to be due to spasm of the internal sphincter or creation of anal fissure.¹⁻³ Topical medications to aid in pain relief are well studied and accepted due to their ready availability and low side effects. Calcium channel blockers (CCB), such as diltiazem and nifedipine, are available in topical preparation, and are thought to aid in pain relief by decreasing internal sphincter spasm.³⁻⁴ Whilst there are some studies accessing the role of CCB in post haemorrhoidectomy pain relief, most are focussed on diltiazem despite the better purported healing rates of nifedipine.⁵⁻⁶

Aims

1. The study hypothesis is that topical nifedipine (0.5%) ointment, compared to topical placebo alone, leads to a significant reduction in pain experienced by patients following haemorrhoidectomy
2. Additionally, that topical nifedipine ointment leads to less usage of rescue oral opioid analgesia by patients
3. Lastly, that there is no significant differences in adverse events between those receiving the topical nifedipine ointment intervention versus those receiving the placebo ointment

Methods

- Sixty patients will be randomly assigned to either the nifedipine group or the placebo group
- Both groups will have a standardised oral analgesia regime in addition to their topical ointment
- Post haemorrhoidectomy pain will be measured using a validated visual analogue pain scale at various time points
- Secondary outcomes of oral opioid rescue analgesia usage and adverse effects will also be recorded

Visual Analogue Scale



Results

- This study is registered in the Australia New Zealand Clinical Trials Registry (ANZCTR N12623000514606p)
- A manuscript of the trial protocol has been accepted for publication in the British Journal of Surgery (BJS) Open
- Recruitment by the Colorectal Department of Surgery at Cabrini Health is anticipated shortly

Conclusion

- This trial will provide new clinical insight into the use of nifedipine in the management of post haemorrhoidectomy pain and dissemination of the results will likely be incorporated into future surgical guidelines

References

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