The use of topical anaesthetic for paediatric pulsed dye laser procedures without a general anaesthetic: a feasibility pilot randomised controlled trial.

ACTRN12623000494639

Status	RECRUITING
Phase	Phase 2
Sponsor	Queensland Children's Hospital
Enrollment	50 participants

Plain Language Summary

Birthmarks, haemangiomas, and scars in children are sometimes treated with pulsed dye laser therapy — a procedure that uses focused light to target abnormal blood vessels or scar tissue. When this is done without a general anaesthetic, children experience some discomfort. A numbing cream (topical anaesthetic) applied beforehand might reduce this pain, but its benefits haven't been formally tested in this setting.

This feasibility pilot trial at Queensland Children's Hospital will look at whether using a numbing cream called Numit is practical and acceptable for children having awake laser procedures. It will also look at whether children who receive it report less pain than children who receive a placebo cream. The information gathered will be used to design a larger, definitive trial.

Your child may be eligible if they are under 18 and are scheduled for a pulsed dye or Nd:YAG laser procedure without general anaesthesia for a scar or vascular birthmark. Children with allergies to local anaesthetics, those under 12 months taking certain medications, and children with specific skin or health conditions are not eligible.

Key Eligibility Criteria

Inclusion (3)

- Children <18 years of age
- Undergoing laser procedures (pulsed dye or Nd:YAG laser) without a general anaesthetic
- Pulse dye laser procedure may be conducted for either scars or vascular anomalies.

Exclusion (14)

- Children who receive any other topical analgesic agents on the area to be lasered, as this can interfere with their pain sensation at the site and hence pain scores
- Children who take oral analgesic medications regularly, as their intraoperative pain sensation may be influenced by their regular medication regimen and not be reflective of the standard patient group experience
- Children with known allergies to prilocaine, lidocaine, or any local anaesthetics of the amide type, as these are contraindications for the treatment agent, and would render participation in the trial unsafe for the child
- Children with known allergies to Numit cream excipients (ethoxylated hydrogenated castor oil, carbomer 934P, sodium hydroxide), as this is a contraindication for the treatment agent, and would render the child's participation in the trial unsafe
- Children with a personal or family history of glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methaemoglobinaenaemia, and children with atopic dermatitis or molluscum contagiousum, as these are either contraindications for the treatment agent or have been associated with local reactions to the treatment agent

... and 9 more (see full listing online)

Locations (1 total)

- QLD, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12623000494639