The Butterfly study. A trial assessing acceptability and safety of using a subcutanous catheter to administer enoxaparin (Clexane) in patients requiring long-term therapy for treatment or prevention of blood clots.

ACTRN12622001059752

Status	RECRUITING
Sponsor	Monash Health
Enrollment	40 participants

Plain Language Summary

People who need long-term blood thinning medication (such as enoxaparin/Clexane) for the treatment or prevention of blood clots typically need daily injections under the skin. Each injection can be uncomfortable and can cause bruising or local skin irritation over time. A subcutaneous indwelling catheter is a small device inserted under the skin that stays in place for several days, allowing medication to be injected without a new needle puncture each time.

This study tests whether using this type of catheter to administer enoxaparin is safe, effective (producing the same drug levels in the blood as direct injections), and preferred by patients. Blood tests will be used to check that the medication reaches therapeutic levels. Participants will also rate their comfort and preference between the catheter method and standard injections.

You may be eligible if you are 18 or older, are currently receiving enoxaparin (at either a prophylactic or therapeutic dose), have been on a stable dose for at least a week, expect to continue for at least 4 more weeks, and can demonstrate the ability to self-inject using the catheter. People on dialysis (other than peritoneal), with recent acute blood clots, or at high risk of bleeding are not eligible.

Key Eligibility Criteria

Inclusion (6)

- Adults 18 years or older and able to provide informed consent currently receiving either prophylactic or therapeutic dose enoxaparin
- Stable on current enoxaparin dose for at least one week
- Anticipated duration of enoxaparin therapy 4 weeks or longer
- Able to demonstrate competency at self-injecting via subcutaneous catheter
- No risk of major bleeding, as per clinician discretion

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

Exclusion (9)

- Unable to provide informed consent
- Haemodialysis dependent renal failure (peritoneal dialysis permitted at PI discretion)
- Inability to comply with testing and follow-up requirements
- Contraindication to anticoagulation therapy
- Acute thrombosis (within 4 weeks of diagnosis)

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

Locations (2 total)

Monash Medical Centre - Clayton campus - Clayton, VIC, Australia

Auckland, New Zealand

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https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622001059752

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