Use of the GPX Embolic Device in Patients Requiring Embolization

ACTRN12620001194954

Status RECRUITING
Sponsor Fluidx Medical Technology, LLC
Enrollment 20 participants

Plain Language Summary

This is a first-in-human feasibility study testing a new medical device called the GPX Embolic Device, which is designed to block blood flow to specific vessels in the body. Embolization procedures (deliberately blocking blood vessels) are used to treat conditions like kidney tumours, vascular abnormalities, and to prepare for surgery. The GPX device represents a new approach to achieving reliable and lasting vessel blockage.

As a first-in-human study, the primary goal is to confirm the device is safe and to observe early signs of how well it performs. There is no comparison group — all participants receive the device during a standard embolization procedure. Participants are followed up after the procedure to assess safety outcomes and recovery.

You may be eligible if you are 18 or older and have a medical condition that requires a durable embolization procedure (such as a kidney tumour or portal vein treatment), have appropriate anatomy for the device, and are willing and able to attend follow-up visits. People who cannot consent, have systemic infection, or are pregnant or breastfeeding are not eligible.

Key Eligibility Criteria

Inclusion (5)

- •Subject presenting with need for durable embolization or pre-operative embolization of a distally-flowing tapering vessel (or vessel bed) including vascular tumours (e.g., renal angiomyolipoma, renal cell carcinoma) and portal vein branches.
- •Subject is =18 years of age with an expected lifespan sufficient to allow for completion of study procedure and follow-up visit, if appropriate based on standard of care
- •Subject has been informed of the nature of the study and agrees to its provisions and has provided informed written consent (signed the Participant Information Sheet and Consent Form).
- •Subject must be willing and able to comply with protocol requirements, including all procedures, clinical evaluations, and follow-up visits, if appropriate based on standard of care.
- •Subject has vascular anatomy that meets the requirements of the IFU.

Exclusion (9)

- • Subject unwilling or unable to consent.
- • Subject's access vessel(s) preclude safe insertion of delivery catheter or catheter is unable to be advanced to targeted location.
- • Subject has a known allergy or hypersensitivity to contrast media that cannot be adequately medicated.
- • Subject who is pregnant, or breastfeeding
- • Subject who is judged unable or unwilling to comply with required follow up visit (if follow-up visit is appropriate based on standard of care).

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

Locations (2 total)

Auckland, New Zealand
Canterbury, New Zealand

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620001194954