BASIL Study: A randomised comparison study on the treatment of calcified (hard and concrete-like) coronary artery using the conventional balloon angioplasty prior stenting versus the use of Shockwave Intravascular Lithotripsy (S-IVL) prior to stenting.

ACTRN12620000086965

Status	RECRUITING
Sponsor	Shockwave Medical
Enrollment	60 participants

Plain Language Summary

When coronary arteries (the blood vessels supplying the heart) become blocked with calcium deposits — making them stiff and concrete-like — standard balloon angioplasty before stenting can struggle to crack open these hardened arteries enough for the stent to sit properly. A newer technology called Shockwave Intravascular Lithotripsy (S-IVL) uses sonic pressure waves — similar to the technology used to break up kidney stones — to shatter the calcium from the inside of the artery, potentially making stenting much more effective.

This randomised trial at North Shore Hospital in Auckland directly compares S-IVL with standard balloon angioplasty in patients with heavily calcified coronary artery disease. Participants are followed up at 30 days to compare procedural success, complications, and clinical outcomes.

You may be eligible if you are 18 or older and are undergoing coronary angiography that reveals a heavily calcified blockage (more than 60% narrowing in an artery at least 2.5mm wide). People who have recently had a major heart attack (STEMI), are in cardiogenic shock, are pregnant, or are already in another device trial are not eligible.

Key Eligibility Criteria

Inclusion (2)

- Patients undergoing coronary angiography who is found to have significant calcified coronary stenosis are eligible. Coronary artery stenosis is defined by either qualitative or quantitative coronary angiography with more than 60% diameter stenosis in equal or greater than 2.5 mm reference vessel diameter of coronary artery with severe calcification.
- Assessment by intravascular ultrasound (IVUS) with presence of greater than 270° arc of calcification at worst point in lesion. If IVUS cannot be delivered, inclusion can be made by angiographic appearance of heavy calcification.

Exclusion (7)

- • Participant is currently enrolled in another research study involving an investigational agent (pharmaceutical, biologic, or medical device) that has not reached the primary endpoint.
- • Participant is pregnant or nursing (a negative pregnancy test is required for women of child-bearing potential).
- • Participant experienced an acute ST Elevation Myocardial Infarction (STEMI).
- • Patient has contraindication to taking dual antiplatelet therapy for a minimum of 6 months.
- • Patients in cardiogenic shock.

... and 2 more (see full listing online)

Locations (1 total)

Auckland, New Zealand

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000086965