Dextran in Carotid Endarterectomy Trial

ACTRN12609000673246

Status	RECRUITING
Phase	Phase 2
Sponsor	National Stroke Research Institute and John Hunter Health
Enrollment	1,412 participants

Plain Language Summary

This study is testing whether a drug called Dextran (given through a drip into the vein during and after surgery) can reduce the risk of stroke during a procedure called carotid endarterectomy. Carotid endarterectomy is an operation to remove a build-up of fat (plaque) from the artery in the neck that supplies blood to the brain. Small clots can sometimes form during or after this surgery and cause a stroke. Dextran is a fluid that may help prevent clots from forming. The trial compares patients who receive Dextran to those who do not, to see if it reduces the risk of stroke or other complications.

You may be eligible if:
- You are 18 years of age or older
- You have carotid artery narrowing (symptomatic or asymptomatic) that requires a carotid endarterectomy
- Your surgery will be performed under general or local/regional anaesthesia

You may NOT be eligible if:
- You have severe heart failure (NYHA Class 3 or higher), unstable angina, or a recent heart attack within 3 months
- You have significant kidney problems (creatinine above 0.20 mmol/L)
- Your platelet count is below 100,000/mm³
- You have had a previous allergic reaction to dextrans
- You are on warfarin during surgery (unless INR is below 1.5)
- You require simultaneous coronary artery bypass grafting

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (1)

- Symptomatic or a symptomatic carotid artery atherosclerosis considered suitable for Carotid Endarterectomy (CEA) performed under either general or loco-regional anaesthesia.

Exclusion (8)

- Documented history of congestive cardiac failure New York Heart Association Functional Classification equal to or greater than 3 (NYHA=/>GD 3), unstable angina or acute myocardial infarction within 3 months of surgery.
- Renal impairment as measured by a serum creatinine of greater than 0.20 mmol/l.
- Thrombocytopaenia of less than 100,000/mm3.
- Previous hypersensitivity to dextrans.
- Concomitant ipsilateral balloon and/or stenting procedure with CEA.

... and 3 more (see full listing online)

Locations (1 total)

Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12609000673246

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