

The ReShAPE trial: Reverse Shoulder Arthroplasty for treatment of Proximal humeral fractures in the Elderly

ACTRN12616000345482

Status	RECRUITING
Sponsor	Dr Geoffrey Smith
Enrollment	60 participants

Plain Language Summary

This study compares two treatments for a type of complex shoulder fracture (3- or 4-part proximal humerus fracture) in older adults: surgery to replace the broken shoulder joint with a reverse total shoulder prosthesis, versus non-surgical treatment (wearing a sling and rehabilitation). These fractures are common in elderly people who fall, and there is currently no strong evidence about whether surgery is better than non-surgical care. Participants are followed for two years.

You may be eligible if:

- You are 70 years of age or older
- You have a 3 or 4-part shoulder fracture (as classified by your surgeon)
- You are medically well enough for surgery
- The fracture happened within the past 28 days
- You live independently (including hostel accommodation)
- You have no other major injuries
- You are able to return for follow-up over 2 years

You may NOT be eligible if:

- You have cognitive difficulties or limited English that prevents you from giving informed consent
- You have a pre-existing condition on the affected side severely limiting shoulder movement (e.g. stroke, previous surgery)
- The fracture was caused by cancer
- You have other injuries on the same arm needing surgery
- The fracture is open, involves the socket, or has split the head of the bone
- You have nerve damage to the arm (axillary nerve palsy)

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

Key Eligibility Criteria

Inclusion (7)

- or 4 part proximal humerus fracture according to the Neer classification
- Medically fit for surgery
- Patient 70 years of age or older
- Presentation within 28 days after injury
- Independent living (including hostel accommodation)
- ... and 2 more (see full listing online)

Exclusion (10)

- inability to consent (limited cognitive capacity judged by 3 or more errors on the mini- mental status examination 6 item screener or limited English proficiency)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616000345482>

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- Pre-existing injury or condition of the affected side which severely affected the movement of the shoulder (eg CVA, pre-existing shoulder pathology, previous fracture or surgery)
 - Pathological fracture
 - Other injury to the same upper limb requiring surgery
 - Open fracture
- ... and 5 more (see full listing online)

Locations (11 total)

St George Hospital - Kogarah, ACT,NSW, Australia
The Sutherland Hospital - Caringbah, ACT,NSW, Australia
Prince of Wales Hospital - Randwick, ACT,NSW, Australia
... and 8 more locations