

Evaluating the Safety and Efficacy of the ROMAX Resurfacing System in patients undergoing hip resurfacing.

ACTRN12625000948493

Status	RECRUITING
Sponsor	Medacta Australia Pty Ltd
Enrollment	280 participants

Plain Language Summary

Hip resurfacing is an alternative to total hip replacement that preserves more of the patient's own bone. Rather than replacing the entire hip joint, the surgeon caps the femoral head (ball of the hip) with a metal component. This approach is particularly popular with younger, more active patients because it can be revised to a total hip replacement later if needed. This study evaluates the ROMAX Resurfacing System from Medacta, testing how well it performs clinically over a three-year follow-up period.

Participants who receive the ROMAX device as part of their planned hip resurfacing surgery will be followed up with questionnaires about pain, function, and quality of life, as well as X-rays to check the implant's positioning. Researchers will track whether any revisions (repeat surgeries) are needed and compare this rate to other resurfacing systems on the Australian market.

You may be eligible if you are a skeletally mature adult (18 or over), scheduled for primary (first-time) hip resurfacing for non-inflammatory joint disease, and are not severely obese (BMI under 40). People with previous hip surgery on the affected side, active joint infection, osteoporosis, metabolic bone disorders, severe anatomical abnormalities, or known allergy to the implant materials would not be eligible.

Key Eligibility Criteria

Inclusion (17)

- Patients scheduled for hip resurfacing, suitable for implantation of a Medacta ROMAX hip resurfacing system according to the manufacturer's indication for use.
 - Skeletally mature adults aged 18 years and over at the time of surgery.
 - Ability and willingness to provide written informed consent for participation.
 - Primary diagnosis of non-Inflammatory Degenerative Joint Disease
 - The subject is classified as morbidly obese (BMI greater than 40)
- ... and 12 more (see full listing online)

Locations (1 total)

VIC, Australia