A Post Recall Clinical Follow-up of patients previously treated with the DePuy Articular Surface Replacement Hip System.

ACTRN12613000781741

Status RECRUITING
Sponsor Massachusetts General Hospital
Enrollment 5,000 participants

Plain Language Summary

This study is following up patients who previously received a specific hip implant system called the DePuy ASR (Articular Surface Replacement), which was recalled due to high failure rates and concerns about metal debris causing tissue damage. Researchers are collecting health and outcome data from these patients over 5 years to monitor how their hips are performing and detect any complications related to the implant.

You may be eligible if:
- You currently have a DePuy ASR XL Acetabular or ASR Hip Resurfacing implant in place (used as intended)
- You are able to give informed consent
- You are able to return for annual follow-up visits for 5 years
- You can complete patient-reported outcome questionnaires

You may NOT be eligible if:
- Your DePuy ASR implant was used in an off-label way
- You received the implant as a revision or conversion procedure
- You have difficulty understanding the consent form
- You refuse to allow your medical records to be reviewed by the study sponsor

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

Key Eligibility Criteria

Inclusion (4)

- Any patient with on-label use of the ASR-XL or ASR component system currently implanted. Manual addition of antibiotics to cement during arthroplasty is not considered to be off-label use.
- Able to provide informed consent at those sites where this is required by the institution's institutional review (IRB) or ethics committee (EC).
- Able to return for follow-up annually for 5 years.
- Able to complete the required patient reported outcome measures.

Exclusion (4)

- Any patient with off-label use indications for the ASR-XL or ASR component system.
- Any patient who received the ASR-XL implant as a result of a hip resurfacing conversion or a revision THA.
- Patients with difficulty in comprehending the Informed Consent Form for any reason.
- The patient refuses to allow their medical records to be inspected by the Sponsor, representatives of the Sponsor, or the medical office staff.

Locations (1 total)

Sportsmed SA Hospital - Stepney, NSW,SA,VIC, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12613000781741