ISRCTN82045842 https://doi.org/10.1186/ISRCTN82045842

Randomised study comparing the metal ions released from two different hip resurfacing devices

Submission date
17/02/2017

Recruitment status
No longer recruiting

Registration date
02/03/2017

Overall study status
Completed

Last Edited
26/01/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis of the hip is a common condition that develops with advancing age. It is usually caused by the wear and tear of the cartilage that lines the hip joint, causing bones to rub against each other. This results in pain, stiffness and a loss in mobility. When pain becomes uncontrollable, hip replacement surgery is often performed. Hip replacement surgeries are one of the most common surgeries in the world and have a high success rate. Surgeons and orthopaedic companies have developed a number of hip surgery innovations that are less intensive including resurfacing systems. Hip resurfacing is a bone-conserving surgical procedure where instead of completely removing a part of the hip, the bone is capped with a smooth metal covering. The damaged bone and cartilage is removed and replaced with a metal shell, just as in a traditional hip replacement. Hip resurfacing can allow for patients to pursue physical activities such as running, jumping, and playing sports that are discouraged after a total hip replacement. There are many types of resurfacing devices that are available to surgeons. The Adept Hip resurfacing system has been successfully used in the UK, Europe, Australia and New Zealand and has one of the lowest revision (failure) rates of all hip resurfacing. However, in Canada this procedure has not yet been approved. This study aims to compare the Adept to the current hip resurfacing device used in Canada, the Conserve Plus hip resurfacing device, by measuring the amount of metal ions present in the blood and by following patient progress after surgery.

Who can participate?
Adults between the ages of 18 and 60 who require a hip replacement.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard hip resurfacing device, the Conserve Plus which comes in sizes of 36 mm to 54 mm. Those in the second group receive the Adept device, which is similar to the Conserve plus device but comes in different sizes (48 mm to 58 mm), has a different maker, and has not yet been approved in Canada (but has ten years of clinical history). Participants then undergo the

standard hip resurfacing surgery. Blood samples are taken before samples and at one and two years after surgery. Participants are followed up one and two years after the surgery to measure how well the hip resurfacing worked.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating.

Where is the study run from?
1. Jewish General Hospital (Canada)
2. Ottawa Hospital (Canada)

When is the study starting and how long is it expected to run for?
March 2012 to December 2025

Who is funding the study?
MatOrtho Limited (UK)

Who is the main contact?
Dr Laura Richards

Contact information

Type(s)
Public

Contact name
Dr Laura Richards

Contact details
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Additional identifiers

Protocol serial number
MOP002

Study information

Scientific Title
Prospective randomised controlled study: Adept and Conserve Plus Hip Resurfacing Devices

Acronym
ADEPT Hip Resurfacing

Study objectives

Null hypothesis:
There will be no difference between the devices as this is a non-inferiority study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Jewish General Hospital Canada, 05/04/2016, ref: 15-174

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Participants are randomly allocated to either intervention or control group. Both groups undergo hip resurfacing which is a surgical procedure that involves placing a metal device or cap on the head of the femur. The surgery is done to the standard level of care.

Control group: Participants in this group receive the Conserve plus hip resurfacing system as it is the standard hip resurfacing system used in Canada and is the current standard of care. The Conserve device is composed of cobalt chromium metal and comes in head sizes 36 mm to 54 mm.

Intervention group: Participants in this group receive the Adept hip resurfacing device which is a different device type that is used for the hip resurfacing. Adept hip resurfacing has 13 years clinical history, is CE marked and TGA approved but is not available in Canada. Participants undergo the surgical procedure as per the current standard of care. The Adept device is composed of cobalt chromium metal and is available in head sizes 48 mm to 58 mm. The stem on the femoral component of this device is different to the device in the control control group and the instrumentation varies between the devices as they have different manufacturers.

The participants are followed up one and two years post operative. Participants are required to have blood samples taken both pre operative and post operative and are asked to complete questionnaires at the post-operative appointments.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Conserve plus hip resurfacing system, Adept hip resurfacing device

Primary outcome(s)
Blood metal ions (cobalt and chromium) are measured using blood samples at baseline, one and two years post operative.

Key secondary outcome(s))
1. Pain, function and range of motion in patients are assessed using the Harris Hip Score at baseline, one and two years post-operative
2. Activity level is measured using the UCLA Activity Score at baseline, one and two years post-operative
3. Surgical outcomes are measured by clinical assessments using a scoring system at one and two years post-operative
3.1. Surgical outcomes are measured by radiographs at baseline, six weeks, one year and two years post-operative

Completion date
24/12/2025

Eligibility

Key inclusion criteria
1. Requires primary hip arthroplasties
2. Between the age of 18 and 60 years at time of surgery
3. Good femoral bone stock as determined by the surgeon
4. Understand the conditions of the study and are willing to participate for the length of the prescribed term of follow-up
5. Capable of, and have given, informed consent to their participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
47

Key exclusion criteria
1. Previous metal work in situ
2. Previous femoral or pelvic osteotomy
3. Dysplasia of the hip requiring structural graft
4. Osteopenia or osteoporosis
5. Hepatic or renal insufficiency
6. Contralateral total or resurfacing hip prosthesis, or patients requiring bilateral hip replacement
7. Planning to become, or who are, pregnant

Date of first enrolment
21/11/2016

Date of final enrolment
06/08/2021

Locations

Countries of recruitment
Canada

Study participating centre
Jewish General Hospital
3755 Chemin de la Côte-Sainte-Catherine
Montreal
Canada
H3T 1E2

Study participating centre
Ottawa Hospital
501 Smyth Rd
Ottawa
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K1H 8L6

Sponsor information

Organisation
MatOrtho Limited

Funder(s)

Funder type
Industry

Funder Name
MatOrtho Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes