Registry study: Oxford Fixed Lateral

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The primary objective is to determine the survival rate after two and five years in fixed bearing Oxford lateral PKR with an uncemented femoral component and present patient reported outcome measures (PROMS), range of motion, radiographic findings...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54018

Source
ToetsingOnline

Brief title
ROFL study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
knee artritis, lateral compartment osteoartritis

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: de industrie (Zimmerbiomet) voor een minimaal bedrag,Zimmer Biomet

Intervention

Keyword: knee, lateral, prosthesis, unicompartmental

Outcome measures

Primary outcome

Survival of the prosthesis will be evaluated as the primary outcome. Any change

to the prosthesis after the initial surgery will be seen as a failure.

Secondary outcome

The secondary outcome parameters are PROMS (patient reported outcomes measures,

range of motion, radiographic findings and complication rates.

Study description

Background summary

Compared to medial partial knee replacement (PKR), lateral PKR is much less often performed. The Oxford partial knee is one of the most used prosthesis in PKR. A lot of developments in medial Oxford PKR were successfully integrated in lateral Oxford PKR. However, in lateral PKR mobile bearings carry a higher risk of dislocation. Therefore, surgeons now use more and more the fixed bearing type consisting of a cemented fixed bearing lateral tibial component and an uncemented femoral component. Especially on this combination data is lacking in lateral PKR, while results in medial PKR are encouraging.

Study objective

The primary objective is to determine the survival rate after two and five years in fixed bearing Oxford lateral PKR with an uncemented femoral component and present patient reported outcome measures (PROMS), range of motion, radiographic findings and complication rates.

Study design

A multicentre prospective cohort study

Study burden and risks

No additional risks account for patients in the current study, since all procedures and data collection are already standard of care. Nevertheless, patients who give informed consent will be encouraged to adhere to the follow-up schedule and complete the digital patient reported outcome measures in a timely matter.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Lateral compartment OA with bone on bone
- Primary OA
- Correctable intraarticular valgus deformity
- Full thickness cartilage on the medial side

- Understand the Dutch language

Exclusion criteria

- Ligaments not intact
- Tibial or femoral osteotomy
- Varus alignment
- Patellofemoral grooving or bone loss

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2024
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Oxford fixed lateral partial knee prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-10-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

(Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78738.100.21