The Adler Genus Unicompartmental Knee Prosthesis Post-Marketing Surveillance Study

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The aim of this study is to test the safety and effectiveness of the Genus Unicompartmental knee prosthesis over a period of 10 years.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON53155

Source
ToetsingOnline

Brief title
AGUKPPMSS

Condition

- Bone and joint therapeutic procedures

Synonym
Unicondylar Knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Adler Ortho S.r.l.
Source(s) of monetary or material Support: Adler ortho Srl

Intervention

Keyword: Genus, PMS, Uni-compatimental

Outcome measures

Primary outcome

Implant survival rate keeping revision for any reason as an end point. Implant

survival rate will be elaborated emplying the Kaplan-Meier statistical system.

Secondary outcome

Cohort study

1. Patients oxford Knee Score

2. Knee Society Score

3. EuroQol Score

PROMS are being collected pre-op, 3 months, 6 months and annually after that.

For clinical assesment it will be done at 1, 3, 5, 7 and 10 years

post-operatively. Data will also be entered in the Dutch LROI system

(landelijke register orthopedische implantaten)

X-rays will be checked looking for prosthesis alignment and sign of loosening

or wear.

Study description

Background summary

Knee replacement surgery (arthroplasty) involves replacing a damaged, worn or diseased knee with an artificial joint (knee prosthesis). It is a routine operation for knee pain most commonly caused by arthritis.

Study objective

The aim of this study is to test the safety and effectiveness of the Genus Unicompartmental knee prosthesis over a period of 10 years.

Study design

Multicenter prospective clinical surveillance study

Intervention

Surgical intervention: people recieve a unicondylar knee prosthesis

Study burden and risks

Participating patiënts will undergo a similar treatment as other patients for a uni-condylar knee arthroplasty.

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

- A primary osteoarthritis of one compartment (Medial or Lateral).
- Patients must be between the age of 18 and 80 at the time of consent
- Listed for unicompartmental knee arthroplasty.
- Patients who are willing to give informed written consent
- Absence of any degenerative disease of a progressive nature (e.g. Rheumatoid arthritis)

Exclusion criteria

Progressive local or systemic infection
- Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable
- Severe instability secondary to advance destruction of chondral structures or loss of integrity of the medial, lateral or either cruciate ligament
- Any patient who cannot or will not provide informed consent for participation in the study
- Those whose prospects for a recovery to independent mobility would be compromised by known coexistent, medical problems
- Patient whose BMI exceeds 45
- Any case not described in the inclusion criteria

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	01-10-2017
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Genus Uni-compartimental Knee prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-04-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ISRCTN	ISRCTN14119313
CCMO	NL57306.058.16