Establish implant accuracy with X-PSI Knee System - A multi-center, prospective, non-controlled post market study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON48383

Source
ToetsingOnline

Brief title
X-PSI Knee System

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Knee cartilage wear/ patient specific instrumentation

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer Biomet
Source(s) of monetary or material Support: Zimmer Biomet

Intervention

Keyword: Accuracy, Clinical Follow Up, Patient specific instrumentation, Total Knee Arthroplasty

Outcome measures

Primary outcome

Achievement of mechanical leg alignment in Hip-Knee-Ankle (HKA) frontal plane

(± 3 degrees) with X-PSI Knee System is as accurate as with standard

(non-guided) instrumentation at 4-6 weeks post operation. The X-PSI Knee System

cohort will be compared with current literature (70% of cases within ± 3

degrees). No control group will be studied.

Secondary outcome

Cost-effectiveness as assessed by OR set-up time, surgery time and

post-processing time

Study description

Background summary

Patient-specific instruments (PSI) provide surgeons with an anatomically personalized surgery tool. The newly developed and CE-marked X-PSI Knee System is based on X-rays used to generate a pre-operative 3D model of the knee. The total knee replacement surgery will then be planned according to this 3D model.

Study objective

The main purpose of this study is to evaluate the accuracy of this new PSI system generated by x-rays for total knee arthroplasty (TKA).
Establish the accuracy of the new X-PSI Knee System guides by analyzing early

postoperative (4-6 weeks) imaging data with regards to the mechanical alignment and compare them with preoperative planning imaging data. Mechanical alignment in (hip-knee-ankle (HKA) frontal plane will be measured and compared to the results reported in the literature using a conventional (non-guided) approach where 70% of cases are within ± 3 degrees. The X-PSI pin guides are designed to facilitate a more simplified, efficient and customized TKA procedure compared to conventional, non-guided instrumentation.

Study design

A multi-center, prospective, non-controlled post market study

Intervention

Total knee arthroplasty with the use of patient specific X-ray guides

Study burden and risks

For patients taking part in the study, no additional risks identified as compared to when they would not be part of the study.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient is 18 years of age or older.
- Patient can follow the X-PSI Knee System imaging protocol as part of standard of care procedures.
- Patient gets TKA treatment which follows the criteria of the appropriate Instruction for Use.
- Patient is willing and able to cooperate in the required postoperative standard of care.
- Patient is willing and able to complete scheduled follow-up evaluations as described in the Informed Consent.
- Patient has participated in the study-related Informed Consent process and has signed the Ethics Committee approved Informed Consent

Exclusion criteria

- Patient is unwilling or unable to give consent or to comply with the follow-up program.
- Patient meets exclusion criteria of the appropriate Instruction for Use
- Patients who have any condition which would in the judgement of the Investigator place the patient at undue risk or interfere with the study. Any patient who is institutionalized, or is a known drug abuser, a known alcoholic or anyone who cannot understand what is required from them
- Patient is known to be pregnant

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	04-10-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-09-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
ClinicalTrials.gov	NCT03275246
CCMO	NL69116.028.19