Implementing Robot-assisted knee arthroplasty at a high-volume, peripheral hospital

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Primary Objective: to investigate whether image-based ROSA procedures, which require more preparation time from the surgeon, reduce operation duration and required materials in the operation ward, as compared to imageless procedures, for which ROSA...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON51307

Source
ToetsingOnline

Brief title
ROSA_IMP

Condition

- Bone and joint therapeutic procedures

Synonym
Arthrosis, Osteoarthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: knee arthroplasty, Learning curve, Robot-assisted knee arthroplasty, Surgery duration

Outcome measures

Primary outcome

Operation ward occupation duration (*exit patient #0* to *exit patient #1*, with patient #0 having no TKA or comparable procedure, and patient #1 being operated with ROSA), preparation duration (entry patient to incision), and duration of surgery (incision to *end of surgery*).

Secondary outcome

Logistical Outcomes: Coordination with anaesthesia/recovery ward, number of instrument trays used, number of cases until Zimmer-Biomet support is no longer needed, type of previous and following surgery. Operation ward occupation duration for stand-alone ROSA-procedures (prior and consequent surgeries in ward are not TKAs), and for consequent TKA- or ROSA-procedures.
Procedural Outcomes: Accuracy of surgical plan (#adaptations, #procedures without deviations from plan) including alignment (deviation, #outliers), implant size, and level of resection. Perioperative outcomes include #complications, blood loss, length of hospital stay, medication, use of anaesthesia, analgesia. ROSA outcomes include stability, implant position, mobility, mechanical axis of the leg (data analysed at end of OR procedure).
Clinical Outcomes: 90-day survival implant, survival patient, reason for revision, type of revision, complications, Oxford Knee Score, Knee Society Score, European Quality of Life Questionnaire 5-Dimensions-5L, Visual Analogue

Scale for pain, Pain Catastrophizing Scale, Pain Sensitivity Questionnaire

Study description

Background summary

In 2015, an estimated 30 million adults suffered from osteoarthritis (OA). Thereby, this disease accounts for 3% of all hospitalizations and for 20% of all health care expenditures.1 Advanced OA requires total knee arthroplasty (TKA). In developed countries, the mean utilization rate of TKA is estimated to be 150-200 cases per 100.000 population in 2019,2 and the trend for annual knee arthroplasties is increasing.3
Modern technology applied during surgeries is designed to further improve placement and alignment of the implants, and thereby reducing short- and long-term complications as well as improving patient-reported outcomes. While patient-specific instrumentation has demonstrated promising, yet not convincing results, newest technologies combine the development of surgical plans with peri-operative assessments of outcomes. The first studies of robot-assisted TKAs (RA-TKA) indeed demonstrated better short-term clinical outcomes when compared to conventional manual technique with reduction in radiographic outliers and reduced risks of iatrogenic soft tissues injuries (reduced blood loss and postoperative drainage)4. Few studies suggest that costs and operative time were higher for RA-TKA, but these costs may be offset by clinical improvement and reduced health care utilization in the 90-day period after surgery.5, 6 From a health care provider perspective, purchase of these systems, utilization within institutions required to accompany a variety of surgeries, and manpower to maintain and utilize these systems still adds significant costs. These costs may be reduced by efficient utilization, eg appropriate utilization of the variety of programs offered by these technologies and scheduling.
To our knowledge, no study has assessed the logistics of utilizing RA-TKA in a high-volume, peripheral hospital. Therefore, our aims are to describe logistical, infrastructural costs of utilizing RA-TKA at Zuyderland Medical Center of two programs offered by the ROSA-robot which are image-based and image-less procedures. To understand the causes of efficient utilization, we will perform a detailed characterization of RA-TKA, including the learning curve for maximally efficient surgery duration, and durations and personnel required for ROSA-implementation. Additionally, we will collect data on procedural, clinical and economic outcomes for 90 days, in order to inform cost-efficacy of utilizing ROSA over a relevant period of time.

Study objective

Primary Objective: to investigate whether image-based ROSA procedures, which

require more preparation time from the surgeon, reduce operation duration and required materials in the operation ward, as compared to imageless procedures, for which ROSA will only be used during the operation to assist in placement of the prothesis.

Study design

This is a randomized study, in which one orthopedic surgeon will perform 8 image-based and 8 image-less ROSA-assisted TKAs. Patients are recruited at Zuyderland Medical Center, enrolled pre-operatively and followed up for 90 days post-surgery.

Intervention

Use or Not-use of an surgery-plan, developed usingt he ROSA-software

Study burden and risks

The clinical benefit of ROSA-assisted surgery has yet only been demonstrated in cadaveric studies; the risks associated with this study or group allocation are minimal, because only additional information is offered, and all decisions are made by the operating surgeons. All procedures are deemed safe for clinical practice.

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

* Eligible for primary TKA
* age 40-90 years
* Body-Mass-Index 18.5-50.0 kg/m2
* American Society of Anaesthesiologists Class I-III
* Willingness and capability to understand and follow protocol

Exclusion criteria

* Rheuma-/trauma-indicated knee arthroplasty

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2022

Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	04-02-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL79142.096.21