The effect of ROSA-assisted knee arthroplasty on clinical outcomes

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Primary Objective: to compare improvement in arthrosis symptoms between patients operated with ROSA-assistance and conventionally operated patients.Secondary Objective(s): to compare clinical, procedural, logistic and economic outcomes between...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON56362

Source
ToetsingOnline

Brief title
ROSA RCT

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Joint disorders
- 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,Zimmer-Biomet

Intervention

Keyword: Gait analysis, patient reported outcome measures, Physical activity, robot-assisted knee arthroplasty

Outcome measures

Primary outcome

to compare improvement in arthrosis symptoms between patients operated with ROSA-assistance and conventionally operated patients one year after surgery

Secondary outcome

Patient-reported outcome measures (PROMs), including OKS, EUR5D-5L, WOMAC, Pain Catastrophizing Scale, Pain Sensitivity Questionnaire will be collected through Phillips Vital Health, as explained in 8.1.1.

Surgical outcomes include #complications, duration of surgery, blood loss, length of hospital stay, medication, anesthesia, analgesia and are documented in the surgery report and available through SAP. Stability, implant position, mobility, mechanical axis of the leg will be extracted from the ROSA-software.

Accuracy of surgical plan (#adaptations, #procedures without deviations from plan) including implant size and level of resection and documented during surgery using the ROSA-software. Logistic outcomes of surgery include surgery ward occupation duration including preparation, operation duration (incision to bandage), anaesthesia, transition from one patient to next, and is collected through the BOZIS-system of Zuyderland Medical Center.

Clinical outcomes include alignment of the leg, 90-day and 1-year survival implant and survival patient, reason for revision, type of revision will be retrieved from electronic medical chart abstraction (SAP NetWeaver for Windows

10, V760 Final Release). Alignment (deviation, #outliers) will be assessed before TKA and 3 months after surgery using a CT scan, per (pre-operative) routine practice .

Physical activity and weight bearing will be assessed for 7 continuous days using hip-worn accelerometers.

Metabolic outcomes include metabolic syndrome, body composition and handgrip strength.

Metabolic syndrome will be quantified binary or as continuous scale. Binary classification will be performed per present AHA/NHLBI ATPIII-criteria: at least 3 out of 5 measures:

• waist circumference >=102 cm in men or >=88 cm in women;

• triglycerides: >=150 mg/dL (1.7 mmol/L), or on drug treatment for elevated triglycerides;

• HDL-Cholesterol: <40 mg/dL (1.03 mmol/L) in men or <50 mg/dL (1.3 mmol/L) in women or on drug treatment for reduced HDL-C;

• blood pressure: >=130 mm Hg systolic blood pressure, >=85 mm Hg diastolic blood pressure, antihypertensive drug treatment;

• fasting glucose: >=5.3 mmol/L or on drug treatment for elevated glucose (20).

As continuous variable, we will utilize the Metabolic Syndrome Severity Scale (MSSS) (21, 22):

• Males: -4.5639 + 0.0108*WC - 0.0254*HDL + 0.0040*SBP + 0.9085*ln(Tri)

• Females: -5.8119 + 0.0197*WC - 0.0149*HDL + 0.0067*SBP + 0.8585*ln(Tri)

Body Composition will be measured using bioimpedance analysis (Tanita DC 360 S, Amsterdam, The Netherlands).

Strength and fitness will be assessed as handgrip strength using hand-held dynamometer (Jamar, Sammons Preston, Inc., Bolingbrook, IL, US), and 2-minute walking, 30-second sit-to-stand, and timed-up-and-go tests.

Economic Outcomes

Cost of procedure (to hospital) including operation duration (room & personnel), healthcare costs (to payer) including hospitalizations, medical procedures, medications, outpatient clinic visits etc, productivity costs (paid work due to absenteeism, unpaid work), paid and unpaid care, and their offset to the clinical outcomes (cost-efficiency). Cost of procedure, medical consumption, healthcare and productivity costs will be assessed using validated questionnaires (iMTA Productivity Cost Questionnaire (iPCQ), iMTA Medical Consumption Questionnaire (iMCQ)). Duration until, and quality of, return-to-work will be inquired via previously developed questionnaires. Cost-efficiency of the procedure will be calculated as cost per quality-adjusted life expectancy (QALE)7. Cost-efficiency will be compared between study groups; in addition, the most progressive threshold of cost-efficiency in orthopedic procedures of 50,000$/QALY will be used as reference.8-10 Work (re-)integration will be assessed by validated questionnaires (Work Ability Index WAI, Work Productivity and Activity Impairment WPAI) on autonomy, work productivity, and work-home-interference.

8.1.3 Other study parameters

Other study parameters include gait and proprioception, and will be optional for patients (see study design).

Gait will be assessed using the 3D VICON motion capture system. This system uses 8 infrared cameras to follow movement. This measurement will be executed under expert supervision of Zuyd Hogeschool staff.

Proprioception of the knee will be measured in a motorized carriage. Patients will lay on a hospital bed where their leg is fixed in the motorized carriage. This sled will passively extend and flex the knee. When patients get the sensation of movement, they have to push a button. The reaction time and the angle to sense the movement will be measured digitally.

24/7-glucose profiles will be assessed using continuous glucose monitors (Freestyle Libre, Abbott Medical Nederland B.V., Veenendaal, NL).

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

Longer-term studies, appropriately powered to detect clinically meaningful

differences in patient symptoms have yet to be performed. In addition to filling this knowledge gap, we aim to provide a more comprehensive assessment of functionality by measuring gait, physical activity, ability to work, and more.

Study objective

Primary Objective: to compare improvement in arthrosis symptoms between patients operated with ROSA-assistance and conventionally operated patients.
Secondary Objective(s): to compare clinical, procedural, logistic and economic outcomes between patients operated with ROSA-assistance and conventionally operated patients .

Study design

This is a randomized clinical study, in which 150 will be enrolled to ROSA-assisted knee arthroplasty or conventional knee arthroplasty. Patients are recruited at Zuyderland Medical Center, enrolled pre-operatively and followed up for 10 years post-surgery.

Intervention

ROSA-assisted knee arthroplasty vs conventional knee arthroplasty

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.
The study only requires patients to invest 9 hours of their time, of which one visit is in addition to regular care and takes ~2 hours. A proportion of patients (50%) undergoes additional measurements (~2hours each) that are also not routine clinical practice. These measurements do not carry an increased risk as only daily tasks are being requested to the comfort of the patient, and are performed under experienced, professional supervision.

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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-12-2022
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	19-09-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	12-01-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	04-12-2023
Application type:	Amendment
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	NL79161.096.21