RESEARCH PROTOCOL

Application non-WMO statement

GENERAL INFORMATION

Title	What makes a best performing hospital in hip and knee replacement? Quality improvement using joint registry data.
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Version number	Version 1
Coordinating investigator	Drs. P. van Schie
Principal investigator(s)	Prof. dr. R.G.H.H. Nelissen Dr. P.J. Marang-van de Mheen
Sponsor	Van Rens Fonds
Subsidy application	Annex 1; Subsidy Application; IQ Joint Study
Data delivery agreement	Annex 2; Data Delivery Agreement; IQ Joint Study

RESEARCH INFORMATION

Rationale	Improving quality in knee and hip replacement surgery by frequent feedback of data from the Landelijke Registratie Orthopedische Implantaten (LROI), supplemented with additional data from participating center. In the favorable case patient care will improve.
Study objectives	1) *Retrospective observational study (LROI database)* Gain more insight into variation in Dutch hospital performance on different outcomes after primary hip- and knee replacement. Variation will also be determined when outcomes are combined into hospital performance profiles. In addition, it will be determined to what extent the variation is explained by patient-mix, type of prosthesis, pre-and postoperative processes or other factors. In addition, we want to test to what extent outliers in the annual funnel plot, can be signaled in an earlier phase using Statistical Process Control (SPC) analyses. 2) *Randomized Controlled Trial (RCT)* Test whether an intervention, consisting of frequently feedback of performance data (LROI data and additive data from participating center) and education will improve patient care, expressed in better functional outcomes, fewer complications and more quality

	improving interventions.
Study design	1) *Retrospective observational study* The variation in performance between Dutch hospital will be determined after hip and knee replacement by a *retrospective observational study* using the available data from the Dutch orthopedic implant registry (LROI). 2) *Randomized Controlled Trial* All hospitals performing hip- and/or knee replacement will be invited to participate in the study to test the effectiveness of a multifaceted intervention strategy (see interventions). Participating hospitals will be randomized to an early versus late group. In the first period, the early group will receive the intervention and will be compared with the other group receiving usual care. In the second period, the early group should be able to sustain the interventions in daily practice (so not actively supported anymore) and will be compared with the late group now receiving the intervention.
Study population	1) *Retrospective observational study* All patients who underwent a hip- and/or knee replacement in the period 2014-2016 are extracted from the LROI database. • All data are anonymized, both on patient and hospital level • In this period relevant case-mix factors are available (e.g. ASA class, Charnley comorbidity score, BMI and smoking) 2) *Randomized controlled trial* Eighteen orthopedic clinics that perform hip-/knee replacements.
Inclusion criteria	1) *Retrospective observational study* All patients who underwent hip- and/or knee replacement between 2014-2016 will be extracted from the LROI database. 2) *Randomized clinical trial* All orthopedic clinics where hip- and knee replacement surgery is performed who agree to participate will be randomized.
Exclusion criteria	None
Sample size	1) *Retrospective observational study* <u>Hip:</u> 80.000 patients (2014-2016) <u>Knee:</u> 75.000 patients (2014-2016) 2) *Randomized clinical trial* Power calculation has shown that at least 18 participating hospitals (9 in each arm) are needed to be able to detect a difference in performance on the composite outcome of 70% versus 80% with 80% power and 95% reliability (assuming an

	intra-hospital correlation of 0.02 and a median of 100 procedures per hospital, separately for hip and knee replacement).
Recruitment method	• The Nederlandse Orthopaedische Vereniging (NOV) and the LROI posted a message on their website • The NOV has sent an email to all orthopedic surgeons to bring the study under attention • At this moment 18/18 hospitals will participate in the study
Intervention	*Randomized controlled trial* • Monthly feedback of performance outcomes • Active education on how to use performance outcomes from joint registry data for quality improvement • Create awareness by asking about (type of) improvement activities + their performance in regular surveys. Awareness will also be increased by the education. • Hospitals will be linked to hospital with opposite performance outcomes to exchange information and find areas for improvement.
Main study parameters	1) *Retrospective observational study (LROI database)* • Variation in following outcomes: o Revision rate (<1 year) o Mortality o Patient Reported Outcome Measures (PROMs) 2) *Randomized controlled trial* • The effect of the intervention on: o Number of quality improvement interventions undertaken o Awareness of their own performance o Number of people attending quality meetings o Revision rate; PROMs; Length of stay; Readmissions; Reoperations; Complications (wound infections) o Composite outcome (in which aforementioned variables are integrated)
Statistical analyses	1) *Retrospective observational study* • Variation in hospital performance outcomes, observed versus expected based on patient mix using logistic regression models to calculate expected probability based on total population. The variation is shown in funnel plots. • The extent to which an outlier in the annual funnel plot can be signaled earlier by using SPC techniques. *2) Randomized controlled trial* • Variation in performance outcomes of participating hospital will be compared to performance outcomes in non-participating hospitals before the start of the RCT by using

	LROI data. • Comparing the intervention with the control group after period 1 and after period 2 (see main study parameters) using the appropriate regression analysis depending on the outcome parameter. When looking at patient outcomes, the clustering of patients within hospitals will be taken into account. • Generate a composite outcome and determine the correlation to individual components of the composite outcome. • Reliability of ranking hospitals by using the composite outcome.
Nature and extent of the burden and risks associated with participation	• The participating hospital has to links LROI data to available data from other sources and anonymize them before sending to coordinating investigator. We create a manual and example file to facilitate. • Participation in educational meetings and interviews among orthopaedic surgeons. • The participating centre must report in logbook which quality improving interventions are undertaken and monitor whether these are effective.
Benefits of participating	For participating hospitals, this study is an opportunity to improve their quality of care through a frequent and clear feedback of the collected information in the LROI with additional collected data. The data can give leads to improving patient care and they are able to test a new way of data feedback, with possibilities of earlier detection of deviating performance.
Disadvantages of participating	Some may be hesitant to disclose of the performance data to a buddy hospital and their peers. In addition it takes time for the data link setup and participation in the interviews and educational meetings as well as monitoring performance on improvement activities.
Administrative aspects	Data obtained from the LROI database and data from the participating hospitals will be anonymized and placed on a secure drive.
Publication policy and amendments	Articles will be submitted after approval of all authors.