Risk-benefit and costs of unicompartmental (compared to total) knee replacement for patients with multiple co-morbidities: a non-randomised study, and different novel approaches to minimize confounding (UTMOST)

First published: 16/02/2017

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28022

EU PAS number

EUPAS17435

Study ID

28022

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Although a RCT (TOPKAT) is ongoing to compare unicompartemental (UKR) and total knee replacement (TKR), limited follow-up and restrictive eligibility criteria will limit external validity to a large number of patients with multiple co-morbidities. Our aims are:1.-To validate a number of analytical methods to minimise confounding: we will replicate TOPKAT by analysing the association between UKR (compared to TKR) and post-operative patient reported outcomes (PROMs) amongst participants in the National Joint Registry for England and Wales(NJR) eligible for TOPKAT (ASA grade <3) using different methods, and then test for a difference between the obtained estimates and TOPKAT.-To study the benefits (PROMs), risks (revision, complications), mortality, costs and cost-effectiveness of UKR (vs TKR) amongst NJR participants not eligible for TOPKAT. Methods previously validated will be applied for this second Aim.We will conduct a cohort analysis using routinely collected data from the NJR linked to hospital admission records (HES) and the National PROMs Database.-Primary outcome: post-operative Oxford Knee Score (PROMs).-Secondary outcomes: one and 5-year risks (revision surgery, systemic infection, wound infection, cardiovascular disease, and venous thromboembolism), mortality, health-related quality of life (EQ-5D), hospital costs (as in HES).-Power: Based on published data, >720 UKR and 8,400 TKR recipients in the co-morbidity cohort will have linked PROMs. With an expected standard deviation of 8, power will be 90% to detect a minimally clinically important difference of 2+ points in Oxford Knee Score.-Statistics: Linear regression will be used to study the association between surgery (UKR vs TKR) and post-operative PROMs. Survival models will

be fitted to study time-to-event (one model for each of the proposed secondary outcomes) according to UKR/TKR. Generalized linear models (GLMs) will be used to study costs and their relationship with surgery type.

Study status

Ongoing

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Centre for Statistics in Medicine

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2017

Actual: 12/01/2017

Study start date

Planned: 02/10/2017

Actual: 09/12/2017

Data analysis start date

Planned: 02/04/2018

Actual: 01/10/2018

Date of final study report

Planned: 28/06/2019

Sources of funding

- Other

More details on funding

NIHR HTA, University of Oxford

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Methodology, Health Economics

Main study objective:

Our overarching aims are:1. To study the validity of different epidemiology analytical methods -used in drug and vaccine studies to minimise confounding- for the assessment of alternative surgical procedures. 2. To apply the identified methods to the analysis of risks, benefits, costs and cost-effectiveness of surgical alternatives for knee replacement for patients with multiple comorbidities.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Knee arthroplasty

Knee operation

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

380000

Study design details

Outcomes

Post-operative Oxford Knee Score (PROMs). One and 5-year risks (revision surgery, systemic infection, wound infection, cardiovascular disease, and venous thromboembolism), mortality, health-related quality of life (EQ-5D), NHS hospital costs (as identified in HES).

Data analysis plan

In the first stage, different methods will be tested to evaluate the association between knee replacement type and both primary and secondary outcomes in the comparison cohort: 1.Propensity score (PS) methods, 2.High-dimensional PS, and 3.Instrumental variable analyses. A chi square test for heterogeneity will be used to formally test for differences between the estimates obtained in TOPKAT compared to the different observational analyses. In a second stage, those methods able to obtain results equivalent (i.e. not significantly different) to the TOPKAT post-operative PROMs findings will be applied to the analysis of the association between UKR (compared to TKR) and all study outcomes (risk/s, revision, benefits, mortality, costs and cost-effectiveness) in the co-morbidity cohort.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Exposure registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No