

Summary of research proposal LROI



Title:

Impact of published safety notices on use of knee implants in daily practice

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Abstract:

If there is a safety concern for specific high-risk implants, such as total knee (TK) implants, it is important medical device (MD) regulators detect such safety concern as early as possible so that they can issue a public safety notice to prevent patient harm. Within the Coordinating Research and Evidence for Medical devices (CORE-MD, an EU funded Horizon2020 grant) study (www.core-md.eu) we have used a recently developed and validated post-market surveillance tool for data web scraping to identify 787 published safety notices associated with 38 unique TK-implants on websites from national competent authorities across 13 countries. Although such safety notices are published to improve safe use of the device and ultimately patient safety, it is unknown whether these are noticed by hospitals and orthopaedic surgeons who decide on what implant to use. In other words, it is unknown whether publication of safety notices changes the use of these TK-implants in daily clinical practice.

For this observational study, the 38 TK-implant as mentioned in the safety notices will be matched to registry data based on brand name and design characteristics (fixation, liner congruence, fixed or mobile liners, patella resurfacing and stabilization). Using interrupted time series analysis, we will examine whether first publication of a safety notice for a specific TK-implant is associated with a change in level and/or trend of use in the Netherlands. The number of primary procedures for a specific TK-implant as a percentage of all primary TK-procedures in a quarter will be calculated over time (2007-2022), allowing for sufficient data points before and after publication of the safety notice. The quarter in which the safety notice is published will be taken as the intervention start. In case of small numbers, we will calculate half-year or yearly percentages. In case of multiple safety notices for the same TK-implant, we will use the last publication date in sensitivity analyses to examine whether this changes the results.

The change in level and/or trend from the interrupted time series analysis will be compared depending on the type of problem described in the safety notices. To explore reasons for continued use over time despite published safety notices, we will also examine revision rates of the specific TK-implants over time compared with other comparable TK-implants (defined by the above design characteristics).

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