Summary of research proposal LROI

Title:
Amplify a clinical trial with data from an implant registry

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Abstract:
The generalisability of the outcome of clinical trials is often considered limited. There might be a discrepancy between data derived from clinical trials and real world data. The aim of this study is to amplify randomized clinical trial data with observational registry data.

Patients who underwent uncemented primary total hip arthroplasty (THA) between 2007 and 2017 are eligible for inclusion. To explore differences and similarities between clinical trial data and registry data, we will compare our CUSTOM database (Collum Femoris Preserving (CFP) and Zweymüller implants), with the LROI database of patients who received one of these implants, but did not participate in the CUSTOM trial. We will match CUSTOM trial participants to one or more registry patients based on the available baseline and surgical characteristics. The main outcome is implant survival up to 10 years follow up.

The results will provide important insight in the survival of the CFP and Zweymuller implants in trial participants and in the total population in the Netherlands. Amplification of clinical trials with data from an implant registry may be a very efficient way to strengthen the power and conclusions of randomized clinical trials.

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