

## 1. Protocol Synopsis: 1 page maximum

Note: This synopsis fits best a prospective clinical trial. Adapt as needed for other type of studies.

PROJECT TITLE	Influence of Preoperative Factors on Functional Recovery after Primary Total Knee Arthroplasty
BACKGROUND	Total knee arthroplasty (TKA) is a widely used intervention and the treatment of choice in the management of severe knee osteoarthritis. However, up to 19% of patients are still unsatisfied after TKA and up to 37% reported limited function improvement. Studies have already tried to determine if patients' characteristics before TKA are associated with functional status after surgery. Results show that preoperative pain and function are important predictors of functional outcome and patient's satisfaction post-surgery. Although functional recovery is still one of the most important preoccupations of patients after TKA, there is still a lack of objective knowledge on which combinations of preoperative factors have the greatest influence on functional recovery after TKA.
PRIMARY OBJECTIVE(S)	To determine which combination of preoperative factors has the greatest influence on functional recovery after a primary TKA in terms of biomechanical gait, pain, function, quality of life and patient's satisfaction.
INCLUSION/EXCLUSION CRITERIA	First joint surgery; presence of severe osteoarthritis disease; minimal walking distance of 10 meters; absence of vestibular, neurological, or musculoskeletal disorders affecting their balance and capacity to walk.
RANDOMISATION/STUDY GROUPS/SAMPLE SIZE	100 patients scheduled for a total knee replacement and a minimum of 30 healthy volunteers aged matched with the patients groups
INTERVENTION	Total knee arthroplasty
FOLLOW-UP	Clinical and three-dimensional gait evaluations pre-arthroplasty and at 3 months and 1 year post-arthroplasty.
ENDPOINT(S)	This research will bring new and relevant insights about which factors (clinic and/or biomechanics) have the greatest influence on TKA outcomes. This project will help to identify patients at risk to have poor outcomes prior to intervention.
STATISTICAL ANALYSIS	A binary logistic regression will be performed. For each patient, all preoperative factors will be entered as the covariates into a forward stepwise regression model. Based on independent analysis and correlation analysis, variables will be added to the step forward regression model respecting the importance of significance ( <i>P</i> value) obtained for each significant variable. Analysis of variance will be used to compare control and patient groups.
TIME FRAME	3 years
REQUESTED BUDGET	CHF (272 933) TOTAL YEAR 2011 (89 055 CHF) TOTAL YEAR 2012 (90 978 CHF) TOTAL YEAR 2013 (92 900 CHF)