Can Patients Perform a Home-Based High-Intensity Interval Training Program Before Undergoing (Revision) Arthroplasty? A Pilot Study to Assess Feasibility

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Main Objectives: 1) Are patients with ASA III score undergoing primary or revision arthroplasty of the knee or hip, able to safely participate in a home-based preoperative High Intensity Interval Training (HIIT) program? 2) Does average daily...

Ethical reviewApproved WMOStatusRecruitingHealth condition typeJoint disordersStudy typeInterventional

Summary

ID

NL-OMON53599

Source

ToetsingOnline

Brief title

Prehabilitation study

Condition

Joint disorders

Synonym

Prehabilitation, preoperative exercise

Research involving

Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum

Source(s) of monetary or material Support: Reinier Haga Orthopedisch Centrum

Intervention

Keyword: High-intensity interval training, Home-based exercise program, Prehabilitation, Revision arthroplasty

Outcome measures

Primary outcome

Primary parameters are study compliance and level of physical activity during 4 weeks prior to surgery

Secondary outcome

Secondary parameters are complications within 30 days after surgery, independence during functional activities as measured by the modified Iowa Level of Assistance Scale (mILAS), length of hospital stay and discharge destination

Study description

Background summary

Preoperative exercise training has shown to reduce complication rates and length of hospital stay after cardiac and abdominal surgery. One of the rationales is that preoperative exercise training induces mild cardiac ischemia, which adapts the heart*s physiology resulting in fewer complications. In the literature, the effects of preoperative exercise training remain inconclusive after arthroplasty. It has been suggested that those studied patients are generally too fit to accomplish large benefits from preoperative exercise. Patients who are more frail, deconditioned and who undergo more elaborate procedures may be more susceptible to benefits from preoperative exercise. In addition, more studies on home-based preoperative exercise programs are needed, since in-hospital programs are more likely to have participants that are more able-bodied and motivated, while the patients who

would need it most are the hardest to reach in these programs. Although we think it will be challenging to mobilize this patient population, we hypothesize that they will benefit from the effects of a home-based preoperative exercise training program.

Study objective

Main Objectives: 1) Are patients with ASA III score undergoing primary or revision arthroplasty of the knee or hip, able to safely participate in a home-based preoperative High Intensity Interval Training (HIIT) program? 2) Does average daily physical activity increase when patients participate in a home-based preoperative HIIT program compared to standard care, when measured with an activity tracker? Secondary Objectives: 1) Does a preoperative training program decrease postoperative complications (< 30 days) after revision arthroplasty of the knee or hip? 2) Does a preoperative training program shorten length of hospital stay after revision arthroplasty? 3) Does a preoperative training program alter discharge destination after revision arthroplasty?

Study design

prospective single-blind pilot trial

Intervention

A preoperative home-based high-intensity interval training program 4 weeks prior to surgery.

Study burden and risks

The burden of participation in this study consists watching an informational video, completing a daily diary, wearing the GENEActiv wrist device and, perform in a high-intensity interval training program. The risks of participating in the training program are minimized by having a licensed physiotherapist tailor the training program to each individual*s abilities. The expected benefits from performing the training program are better fitness levels, fewer complications, shorter length of stay and more often discharge to the own home environment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- On waiting list or planned for primary or revision arthroplasty of the hip or knee at the Reinier Haga Orthopedisch Center (RHOC)
- Classified with an ASA score of III
- As long as a joint infection is ruled out or not suspected, we will also include patients that have a Girdlestone or spacer in situ in any joint

Exclusion criteria

- ASA I score, ASA II score, IV and ASA V score
- Revision surgery for isolated cup revision or suspected or confirmed joint infection
- Periprosthetic fracture
- Patient is declared unfit to safely perform the prehabilitation program in an at-home setting by orthopaedic surgeon, physical therapist, researcher, anesthesiologist, cardiologist or other relevant health professional
- Patient-reported allergies to medical grade plastic, PU resin and/or nickel

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 16-09-2024

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 13-09-2023

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

CCMO NL82800.058.23