The feasibility of home monitoring for patients undergoing outpatient surgery for elective hip or knee replacement

Published: 21-12-2021
Last updated: 05-04-2024

The purpose of this study is to evaluate the feasibility of postoperative home monitoring for patients undergoing outpatient knee- or hip arthroplasty; discharged on the same day as surgery; less than 12-hour hospital stay.We hypothesise that a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51009

Source
ToetsingOnline

Brief title
HORATIO: Home monitoring after outpatient primary hip or knee Prosthesis

Condition

- Joint disorders

Synonym
joint degeneration, Osteoartritis

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Philips (sponsort deel apparatuur),Philips NV

Intervention

Keyword: Hip prosthesis, Home monitoring, Knee prosthesis, Outpatient surgery

Outcome measures

Primary outcome

Primary Objective:

The primary outcome is the mean percentage of successful wireless transmissions from home of blood pressure (BP) levels, heart rate (HR), respiratory rate (RR), oxygen saturation (SpO2) levels, temperature and pain score up to and including postoperative day 4 with a feasibility target of >=90%.

Secondary outcome

Secondary Objective:

Patient satisfaction measured with a patient satisfaction survey (5- point Likert scale)

Tertiary Objective:

Cost effectiveness. A cost analysis will be conducted by the Diakonessenhuis Finance Department.

Study description

Background summary

The introduction of fast-track protocols and multidisciplinary perioperative care strategies have shortened the length of stay (LOS) after total joint arthroplasty (TJA) significantly over the last 10 years. Outpatient surgery for hip- and knee prosthesis is now feasible for an estimated 15-20% of patients.

However, these are mainly strictly selected young and healthy patients without comorbidities. We have reasons to believe that home monitoring and real-time interactive support will make outpatient TJA possible for a significantly larger group of patients without increase of complications and readmissions. Furthermore, we expect patient satisfaction will be high and that total care costs will be reduced.

Study objective

The purpose of this study is to evaluate the feasibility of postoperative home monitoring for patients undergoing outpatient knee- or hip arthroplasty; discharged on the same day as surgery; less than 12-hour hospital stay.

We hypothesise that a wireless system is feasible for monitoring patients at home postoperatively combining it with real-time interactive support by a response team in our hospital.

Study design

The HORATIO-study is a prospective observational study

Study burden and risks

Risks:
Falls
Disconnection with patient at home/no data transfer
Readmission in hopsital
Emergency department visit

Benefits:
faster revalidation
Better (real-time) communication with hospital
Rapidly back home in own environment, al own pace and surrounded by family or loved ones
Cost effectiveness

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

Primary unilateral THA, TKA or UKA
Preoperative body mass index (BMI)<40 kg/m2
Age 18-75 years at the time of surgery

Exclusion criteria

ASA score IV
Revised cardiac risk score > 2
Predictive Postoperative Nausea and Vomiting (Apfel) score > 2
Cognitive impairment (e.g. Dementia)
Use of psychopharmaceutical medicine
Chronic obstructive pulmonary disease with FEV1 <= 1
Obstructive sleep apnoea

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2022
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	sensor (Healthdot) for measurement vital signs at home
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-12-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL77324.100.21