Feasibility of a therapeutic exercise before total hip replacement

Submission date	Recruitment status	Prospectively registered
02/09/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
26/10/2009	Completed	Results
Last Edited	Condition category	Individual participant data
26/10/2009	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Feasibility and preliminary effectiveness of a short-term, preoperative therapeutic exercise programme for frail, elderly patients awaiting total hip replacement

Acronym

Profyt2

Study objectives

Is a short-term preoperative therapeutic intervention for frail elderly patients with osteoarthritis awaiting total hip replacement feasible?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of the University Medical Centre Utrecht (protocol number 07/051) and the Gelderse Vallei Hospital (protocol number Profyt 06/184-O) approved this study on the 5th June 2007.

Study design

Randomised controlled single-blind pilot trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Hip osteoarthritis

Interventions

Experimental group: Short-term (3-6 weeks), intensive, tailor-made therapeutic exercise (twice a week).

Usual care group: One information meeting and practicing the use of crutches.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Feasibility towards patients satisfactory is assessed by the following main outcomes:

- 1. The occurrence of adverse effects during testing or training. Participants will have to register any discomforted, stiffness or other adverse events in their diary.
- 2. Adherence to the treatment. Both groups are asked to register their adherence to the home based training programme (i.e. time exercised, days exercised and perceived exertion). Pedometer adherence is defined as the number of steps recorded on the daily pedometer log that met or surpassed the weekly goal. Also adequate use of the diary will be assessed as part of the adherence to the intervention.
- 3. The patients' appreciation and motivation towards the therapeutic intervention will be determined by a patient evaluation form (satisfaction questionnaire) that patients complete at the end of the preoperative training.

Secondary outcome measures

- 1. Preoperative effectiveness:
- 1.1. Aerobic capacity, assessed with the Physical Working Capacity 170
- 1.2. Strength and power of the lower limb muscles is assessed by the chair rise time
- 1.3. Functional mobility is assessed with the Timed Up and Go Test
- 1.4. Walking capacity is assessed with the six minutes walk test (6MWT)
- 1.5. Pain, functioning and quality of life is assessed with the Hip disability and Osteoarthritis Outcome Score (HOOS)
- 1.6. Patient specific complaint (Patient Specifieke Klacht [PSK]) questionnaire
- 1.7. Functional activities are assessed by the Longitudinal Aging Study Amsterdam (LASA) Physical Activity Questionnaire (LAPAQ)
- 2. Postoperative effectiveness:
- 2.1. Length of stay
- 2.2. Discharge destination (home, rehabilitation centre or nursing home)
- 2.3. The patient's functional mobility score using the Iowa Level of Assistance Scale

Overall study start date

05/06/2007

Completion date

09/11/2008

Eligibility

Key inclusion criteria

- 1. Both males and females, age ≥70 years
- 2. Scheduled for elective total hip arthroplasty (THA) (minimum waiting period of 3 weeks)
- 3. Osteoarthritis is the motive for the THA
- 4. First surgical intervention of this pathology
- 5. Scores ≥2 on the Clinical Frailty Scale (CFS)
- 6. Able to permit time for the intervention between enrolment and surgery

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

20

Key exclusion criteria

- 1. Unable to understand Dutch
- 2. Patients with severe heart disease

Date of first enrolment

05/06/2007

Date of final enrolment

09/11/2008

Locations

Countries of recruitment

Netherlands

Study participating centre Hospital Gelderse Vallei

Ede Netherlands 6716 RP

Sponsor information

Organisation

Hospital Gelderse Vallei (Netherlands)

Sponsor details

Willy Brandtlaan 10 Ede Netherlands 6716 RP

Sponsor type

Hospital/treatment centre

Website

http://www.zgv.nl

ROR

https://ror.org/03862t386

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Gelderse Vallei (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration