Driving safely following total hip arthroplasty through an direct anterior approach: investigating brake force and brake response time.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23661

Source
NTR

Brief title
DRIFTH

Health condition

hip arthritis

Sponsors and support

Primary sponsor: n/a
Source(s) of monetary or material Support: n/a

Intervention

Outcome measures

Primary outcome

The main study endpoint is brake force at six weeks, determined by means of a pedal force

meter in a driving simulator.

Secondary outcome

- Brake response time, using a pressure sensor on the brake pedal.
- Brake response time and brake force on the clutch pedal, using the same pedal force meter and pressure sensor.
- Subjective ability to drive, determined by means of a questionnaire that is filled out before and after each measurement session.
- Opioid use (type and dosage) at each measurement point.

Study description

Background summary

Rationale: After total hip arthroplasty (THA), a frequently discussed topic at the six- to eight-week follow-up appointment is the return to driving. For THA through an direct anterior approach (DAA), an emerging surgical technique, driving ability has not been investigated before. This approach leads to faster mobilization and achievement of good short term functional outcomes. Since this approach leads to less muscle damage and less postoperative pain, patients may be able to return to driving earlier than described by the current literature. It is hypothesized that patients can safely return to driving four weeks after right sided THA through DAA and two weeks after left sided THA through DAA.
Objective: The primary objective is to study brake force following THA through DAA. Secondary objectives are brake response time, patient reported confidence to return to driving and opioid use following THA through DAA.
Study design: A prospective, observational cohort study.
Study population: The eligible study population consists of patients above 18y, undergoing elective THA through DAA in the Alrijne hospital, also in possession of a valid Category B driving license.
Main study parameters/endpoints: The main study endpoint is brake force at six weeks, assessed by a pedal force meter in a driving simulator. Baseline preoperative measurements, performed on the operation date prior to surgery, will be compared to postoperative measurements on one day, two weeks, four weeks and six weeks after surgery. Secondary study endpoints are brake response time at six weeks, brake response time and brake force of the left leg on the clutch pedal at six weeks, subjective ability to drive, determined by a questionnaire, and opioid use during follow-up.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects will make two additional hospital visits for measurements and completing a questionnaire, each visit taking a half- to one hour. Car seat position in the driving simulator will be comparable to a normal chair on which patients are allowed to sit after surgery. Thus, no additional pain or discomfort by wound pressure is expected. The benefits for the subjects are to receive some insight in their driving capability during the period of follow-up.

Study objective

It is hypothesized that patients can safely return to driving four weeks after right sided THA through DAA and two weeks after left sided THA through DAA.

Study design

All outcome at:
- Preoperative
- Postoperative day 1
- Postoperative week 2
- Postoperative week 4
- Postoperative week 6

Contacts

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Eligibility criteria

Inclusion criteria

- Age above 18 years
- Male or female
- Left THA or right THA
- In possession of a valid Category B driving license

Exclusion criteria

- Illiteracy or insufficient command of the Dutch language

- Chronic opioid consumption
- Neurological disorders which affect response time (e.g. Parkinson’s disease, MS)
- < 1 year following arthroplasty in the lower extremity
- Disabling gonarthrosis or contralateral coxarthrosis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9489
Other	METC Leiden | Den Haag | Delft : tbd

Study results