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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23661

Bron
NTR

Verkorte titel
DRIFTH

Aandoening

hip arthritis

Ondersteuning

Primaire sponsor: n/a
Overige ondersteuning: n/a

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint is brake force at six weeks, determined by means of a pedal force meter in a driving simulator.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

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Wetenschappelijk

Alrijne Ziekenhuis
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9489
Ander register	METC Leiden | Den Haag | Delft : tbd

Resultaten