Captain Morgan Study

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Compared to the Allis technique, the Captain Morgan technique is more effective in reduction of posterior dislocations of total hip prostheses using procedural sedation and anesthesia in the emergency room

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20769

Bron
NTR

Verkorte titel
TBA

Aandoening

Posterior disclocation of total hip prosthesis

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Total percentage of successfull reduction.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Dislocation of a total hip prosthesis (THP) is a frequent reason for admission to the emergency room (ER). Despite many describes and applied reduction techniques, available literature regarding their effectiveness is surprisingly limited. No direct comparisons of different techniques are described. The largest study regarded the Allis technique. In a small study, the relatively new Captain Morgan technique was found to be considerably more effective. Also, it is associated with less potential health risks for the treating physician.
Objective: The goal of this study is to directly compare effectiveness of the Captain Morgan technique to the Allis technique in reduction of posterior dislocation of a THP using procedural sedation and analgesia (PSA) in the ER.
Study design: Multicenter prospective randomized cohort study.
Study population: Patients, aged ≥ 18 y.o., presenting in the ER with unilateral dislocation of a THP.
Intervention: In one group, the Captain Morgan technique will be used to reduce the hip, in the other group the Allis technique will be used.
Main study endpoint: Total percentage of successful reduction per respective technique.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All treatment aspects used in this study are part of the standard care for the condition. Thus, no additional risks are involved. The only addition to standard care is a request to written informed consent. Participation provides subjects no direct benefits. However, subjects do contribute to future treatment of the condition (considering the sometimes recurrent nature of the condition, they might end up benefitting themselves at a later point in time).

Doel van het onderzoek

Compared to the Allis technique, the Captain Morgan technique is more effective in reduction of posterior dislocations of total hip prostheses using procedural sedation and anesthesia in the emergency room

Onderzoeksopzet

All data will be collected during a subject's stay in the emergency department. No follow-up.

Onderzoeksproduct en/of interventie

In one group, the Captain Morgan technique will be used to reduce the hip, in the other group the Allis technique will be used.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Unilateral posterior dislocation of a total hip prosthesis
- Age ≥ 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Concomittant traumatic findings that complicate reduction or are of greater urgency (e.g. (periprosthetic) fractures of the involved leg of life-threatening injury requering immediate intervention)
- Previously >1 unsuccesfull reducation despite optimal circumstances (a.o. adequate sedation and procedural analgesia).
- No informed consent or refusal of treatment.
- Other reason to perform reduction in the operating room (logistics, personnel).
- Hip prosthesis with a dual mobility cup (these always require reduction in the operating room).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	242
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	02-03-2020
Soort:	Eerste indiening

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	NL8423
Ander register	RPTO MCL : RTPO1086

Resultaten

Samenvatting resultaten
N/A