Modifications in implant features in the TFNA proximal femoral nail as successor of a more conventional intramedullary nail were associated with an increase in fixation failure rate.

Gepubliceerd: 15-12-2020 Laatst bijgewerkt: 13-12-2022

No improvement of fixation failure will be found after the introduction of the TFNA

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21440

Bron
Nationaal Trial Register

Verkorte titel
TFNA vs GTN3

Aandoening

Trochanteric fractures

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Implant related fixation failure

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of this study was to evaluate failure rates of the TFN-Advanced Proximal Femoral Nailing System (TFNA; DePuy Synthes) versus one of its predecessors and to evaluate the responsible mechanisms of fixation failure.
In 2016 the TFNA was introduced in our institution as successor of the Gamma Trochanteric Nail (GTN3; Stryker). All trochanteric fractures treated surgically from 2011 to 2019 were retrospectively reviewed for fixation failure. Patients suffering from pathologic fractures were excluded. Fixation failure was defined as the occurrence of an implant related complication subclassified as implant cut-out, implant breakage, non-union or malpositioning of the screw/blade. For all cases age, gender, body mass index (BMI), smoking status, comorbidity score (American Society of Anesthesiologists (ASA)), fracture type (AO) and implant positioning (tip-apex-distance) were identified. Missing data were imputed via multiple imputation by chained equations. Propensity score matching was used to balance distributions of covariates and to compare failure rates between TFNA and GTN3 groups.

Doel van het onderzoek

No improvement of fixation failure will be found after the introduction of the TFNA

Onderzoeksopzet

Start 07/2020
Finish 02/2021
Implant related fixation failure and the responsible failure mechanism were defined as the occurrence of (1) implant cut-out, (2) implant breakage, (3) non-union, (4) malpositioning of the screw/blade in the femoral head.
Patients were treated with an intramedullary nail following a trochanteric fracture between June 2011 and July 2019. Electronic files were searched for the occurrence of failure in August 2019.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Trochanteric fracture treated with a TFNA or GTN3 nailing system

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

pathological fracture

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	1000
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-12-2020
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	NL9149
Ander register	LHC Rijnstate : 2020-1596

Resultaten