

# 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.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21440

### Source

Nationaal Trial Register

### Brief title

TFNA vs GTN3

### Health condition

Trochanteric fractures

## Sponsors and support

**Primary sponsor:** None

**Source(s) of monetary or material Support:** None

## Intervention

## Outcome measures

### Primary outcome

Implant related fixation failure

## Secondary outcome

Failure mechanism

## Study description

### Background summary

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.

### Study objective

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

### Study design

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.

## Contacts

**Public**

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**Scientific**

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## Eligibility criteria

### Inclusion criteria

Trochanteric fracture treated with a TFNA or GTN3 nailing system

### Exclusion criteria

pathological fracture

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2020

Enrollment:	1000
Type:	Actual

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	15-12-2020
Application type:	First submission

## 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	NL9149
Other	LHC Rijnstate : 2020-1596

## Study results