Incidence and risk of Nail Breakage in patients implanted with the DePuy Synthes TFN-ADVANCED™ Proximal Femoral Nailing System (TFNA)

First published: 26/03/2020

Last updated: 16/01/2023

Study Finalised

Administrative details

EU PAS number

EUPAS34300

Study ID

50577

DARWIN EU® study

No

Study countries

United States

Study description

This is a retrospective cohort study of patients with femur fracture undergoing surgical repair with a cephalomedullary nail system in an inpatient setting. An overall cohort of patients implanted with cephalomedullary nails will be identified between January 2010 (in alignment with FDA approval date of Zimmer Natural Nail) and September 2019 or most recent data. A subset of the overall cohort implanted with TFNA, Stryker Gamma3, or Zimmer Natural Nail between February 2014 (in alignment with FDA approval date of TFNA) and September 2019 or most recent data will be identified to meet some of the objectives including the primary objective. The identified patients will be longitudinally followed for pre-specified time intervals until they experience the endpoint of interest (co-occurring diagnosis of breakdown of internal device AND procedure for femur fracture repair or device removal from femur) or a censoring event (end of hospital participation in PHD, end of risk window, end of study), whichever occurs first. Our rationale for requiring BOTH a diagnosis of breakdown of internal device AND a procedure for femur fracture repair or device removal from femur is due to the ICD-9/10 diagnosis codes for breakdown of internal device which are not specific to the cephalomedullary nails. Presence of a co-occurring procedure to repair a fractured femur or remove a device from the femur helps ensure that the device breakage refers to the device of interest. The graphic below provides a visual representation of the study design.

Study status

Finalised

Research institutions and networks

Institutions

Johnson & Johnson

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anna Wallace

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/03/2020

Actual: 23/03/2020

Study start date

Planned: 26/03/2020

Actual: 26/03/2020

Date of final study report

Planned: 31/12/2020

Actual: 02/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson & Johnson

Study protocol

RWE19_SAF_013 TFNA Protocol_Final 2 .pdf (628.04 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To estimate the incidence rate and the relative risk of nail breakage among patients implanted with the DePuy Synthes TFNA Proximal Nailing System compared to patients implanted with selected nails designed to provide cephalomedullary support to a proximal femoral fracture, the Stryker Gamma3 Nail System or Zimmer Natural Nail System.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medical condition to be studied

Femur fracture

Population studied

Short description of the study population

Study population included patients with femur fracture undergoing surgical repair with a cephalomedullary nail system in an inpatient setting identified from the Premier healthcare database from January 2010 to September 2019.
Inclusion Criteria: Cephalomedullary Nail Overall Cohort

• >21 years*, AND

• have an ICD-9/10 procedure code for femur fracture repair with internal fixation device, AND

• be treated surgically with a TFN, TFNA, Stryker Gamma3 or Zimmer Natural Nail cephalomedullary nail in an inpatient setting between January 1, 2010, and September 30, 2019 or most recent data (index procedure)

Inclusion Criteria: Cephalomedullary Nail Sub-cohort

• >21 years*, AND

• have an ICD-9/10 procedure code for femur fracture repair with internal fixation device, AND

• be treated surgically with TFNA, Stryker Gamma 3 or Zimmer Natural Nail cephalomedullary nail in an inpatient setting between February 1, 2014 and September 30, 2019 or most recent data (index procedure)

*Age 21 and older was selected to be in alignment with the TFNA indication, which is for the treatment of fractures in adults and adolescents in which the growth plates have fused.

Exclusion Criteria: Cephalomedullary Nail Overall Cohort & Cephalomedullary Nail Sub cohort

• Missing age or sex on index date

• Presence of nail breakage ICD9/10 diagnosis code on index date

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Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with femur fracture

Estimated number of subjects

12.000

Study design details

Outcomes

Nail breakage, defined as ≥1 ICD-9/10 diagnosis code for breakdown of internal device AND ≥1 ICD-9/10 procedure code for femur fracture repair or device removal from femur co-occuring within the same inpatient hospitalization with admission date between index date + 1 day and index date + 18 months

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Data analysis plan

Descriptive statistics on baseline characteristics with comparison between exposure groups, Unadjusted incidence rate for nail breakage, Multivariate Cox Regression to determine HRs with 95% CI, Sensitivity analyses

Documents

Study publications

Wallace A, Amis J, Cafri G, Coplan P, Wood J. Comparative Safety of the TFN-ADV...

Data management

Data sources

Data source(s), other

Premier Healthcare Database

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No