Evaluation of Functional Recovery after Treatment of Fractures using the IlluminOss® System (IO-ALL study); A Multicenter Prospective Observational Study

Gepubliceerd: 06-01-2016 Laatst bijgewerkt: 18-08-2022

We expect that treating patients with the IlluminOss® System will result in excellent recovery

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

Samenvatting

ID

NL-OMON27661

Bron
NTR

Verkorte titel
IO-ALL

Aandoening

Fractures treated with the IlluminOss® System

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Erasmus Medical Center, Medical Research Ethics Committee (MREC)
Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of patients treated per indication

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND
In 2009, the IlluminOss® System (IlluminOss® Medical, East Providence, RI, USA) received CE mark clearance for minimally invasive use in the treatment of fractures of light to low load bearing bones. Its presumed benefits are 1) shorter operative time (as the percutaneous insertion requires less time than open invasive surgery); and 2) shorter length of hospital stay due to earlier (weight bearing) mobilization and resulting ADL independence. There is currently no overview for which indications the IlluminOss® System is being used nor of the treatment results.

AIM
The main aim of this study is to determine how often and for which indications patients are treated with the IlluminOss® System. Secondary aims are to determine for subgroups with the same fracture type; 1) the hospital length of stay; 2) the time until discharge from follow-up; 3) the rate of complications (with associated treatment); 4) the Range of Motion (ROM) of the affected and contralateral side (only for extremity fractures); 5) the time to regaining independence in activities of daily living (ADL); and 6) the patient-reported quality of life, disability, functional outcome and pain.

STUDY DESIGN
Multicenter Prospective Observational Study (case series)

POPULATION
Study population: Adult patients (18 years or older) with a fracture that was treated with the IlluminOss® System.

INTERVENTION
Closed reduction and percutaneous intramedullary fixation using the IlluminOss® System

ENDPOINTS
Primary outcome measure: Number of patients treated per indication.

Secondary outcome measures: Hospital length of stay; Time until discharge from clinical follow-up; Complications with associated treatment; Range of Motion (for extremity fractures only); Time to regaining independence in activities of daily living (ADL); Patient-reported quality of life, disability, functional outcome, and pain (as applicable: Short Form-36 (SF-36), Short Musculoskeletal Functional Assessment (SMFA),Disabilities of the Arm, Shoulder, and Hand (DASH), Patient-Rated Wrist Evaluation (PRWE), and Lower Extremity Functional Scale (LEFS)).

PROM’s will completed at 2 and 6 weeks, and at 3, 6, and 12 months after surgery.

RECRUITING COUNTRIES
The Netherlands

Doel van het onderzoek

We expect that treating patients with the IlluminOss® System will result in excellent recovery

Onderzoeksopzet

Baseline, 2 weeks, 6 weeks, 3 months, 6 months, 12 months

Onderzoeksproduct en/of interventie

Closed reduction and intramedullary fixation using the IlluminOss® System

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Adult men or women with an age of 18 years or older (no upper age limit)

2. Patients with a fracture treated using the IlluminOss® System*

3. Provision of informed consent by patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients unwilling or unable to comply with the after-care protocol and follow-up visit schedule

2. Insufficient comprehension of the Dutch language to understand the rehabilitation program and other treatment information in the judgment of the attending physician

3. Participation in another surgical intervention or drug trial.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-01-2016
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	NL5500
NTR-old	NTR5635
Ander register	: MEC-2015-732 (METC Erasmus MC)

Resultaten

Samenvatting resultaten
None yet; study is ongoing