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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27661

Source
NTR

Brief title
IO-ALL

Health condition

Fractures treated with the IlluminOss® System

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Erasmus Medical Center, Medical Research Ethics Committee (MREC)
Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

Number of patients treated per indication

Secondary outcome

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))

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

Closed reduction and intramedullary fixation using the IlluminOss® System

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2016
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	06-01-2016
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	NL5500
NTR-old	NTR5635
Other	: MEC-2015-732 (METC Erasmus MC)

Study results

Summary results
None yet; study is ongoing