Functional Recovery after Treatment of Extra-Articular Distal Radial Fractures in the Elderly using the IlluminOss® Photodynamic Bone Stabilization System (IO-Wrist); 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-OMON28700

Source
Nationaal Trial Register

Brief title
IO-Wrist

Health condition

Distal radius fractures

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: IlluminOss Medical Inc, East Providence, RI, USA

Intervention

Outcome measures

Primary outcome

Disabilities of the Arm, Shoulder, and Hand (DASH) score

Secondary outcome

Patient-Rated Wrist Evaluation (PRWE); Pain (VAS and analgesic use); Short Form-36 (SF-36); EuroQoL-5D (EQ-5D); Time to regaining ADL independence; Time to return to daily activities and work; Range of motion of the wrist; Radiographic evaluation; Complications and secondary interventions; Health care consumption with associated costs; Productivity loss with associated costs

Study description

Background summary

BACKGROUND

Up to 30% of patients with a distal radius fracture suffer from long-term functional restrictions after non-operative treatment. The IlluminOss® Photodynamic Bone Stabilization System (PBSS) is a novel implant. It comprises intramedullary fracture fixation using a percutaneous approach. The percutaneous nature of the operative procedure is aimed at reducing the risks associated with traditional open reduction and internal fixation. Operative fixation with the IlluminOss® PBSS allows for early mobilization and may theoretically lead to earlier functional recovery and earlier ADL independence than plaster immobilization.

AIM

The primary aim of this prospective, multicenter, observational study is to examine the DASH (Disabilities of the Arm, Shoulder, and Hand) score in elderly patients who sustained a unilateral displaced distal radius fracture (DRF) that was treated with the IlluminOss® Photodynamic Bone Stabilization System. Secondary aims are to assess the effect on treatment on functional outcome, pain, health-related quality of life, time to regaining ADL independence, time to resumption of daily activities and work, ROM, complications, and costs for health care use and lost productivity in these patients.

STUDY DESIGN

Multi-center observational study. Approximately 4-6 hospitals in the Netherlands will participate.

POPULATION

Elderly patients (60 years or older; independent in activities of daily living) with a unilateral displaced distal radius fracture (AO type 23-A2 and 23-A3) that was successfully closed reduced within 12 hours of presentation to the Emergency Department and treated with the IlluminOss® Photodynamic Bone Stabilization System within 14 days are eligible.

INTERVENTION

Closed reduction and percutaneous intramedullary fixation using the IlluminOss® Photodynamic Bone Stabilization System

ENDPOINTS

Primary outcome measure: DASH score.
Secondary outcome measures: functional outcome (PRWE); pain (VAS); health-related quality of life (SF-36 and EuroQoL-5D); ADL independence; work/ADL resumption; ROM; radiological outcome; complications; costs for health care use and lost productivity.

Primary and secondary outcomes will be determined 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 PBSS will result in excellent functional recovery of function (i.e., low DASH and high PRWE and ADL scores) within three months after trauma.

Study design

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

Intervention

Closed reduction and intramedullary fixation using the IlluminOss® Photodynamic Bone Stabilization System

Contacts

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Eligibility criteria

Inclusion criteria

1. Adult men or women with an age of 60 years or older (no upper age limit)

2. Patients with a unilateral extra-articular displaced distal radius fracture (AO type 23-A2 or 23-A3)

3. Capable of independent activities of daily living prior to index injury

4. Closed reduction and intramedullary fixation using the IlluminOss® PBSS within 14 days after trauma

5. Provision of informed consent by patient

Exclusion criteria

1. Additional traumatic injuries if this affects treatment, rehabilitation, or function of the affected hand

2. Patients with a pathological, recurrent, or open (i.e., Gustilo grade II or III) fracture

3. Patients with an impaired wrist function at the affected side due to arthrosis, rheumatoid disorder, or neurological disorder prior to the injury

4. Patients with a bone disorder which may impair bone healing, excluding osteoporosis (e.g., Paget’s disease, renal osteodystrophy, osteomalacia)

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

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

7. Participation in another surgical intervention or drug study

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):	01-07-2015
Enrollment:	50

Type: Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 29-09-2015

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	NL5233
NTR-old	NTR5457
Other	METC Erasmus MC : MEC-2015-283 (METC Erasmus MC)

Study results

Summary results
Hagenaars T, Van Oijen GW, Roerdink WH, Vegt PA, Vroemen JP, Verhofstad MHJ, Van Lieshout EMM.
Functional recovery after treatment of extra-articular distal radius fractures in the elderly using the IlluminOss® System (IO-Wrist); a multicenter prospective observational study. BMC Musculoskelet Disord. 2016 May 27;17:235.