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

Gepubliceerd: 29-09-2015 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON28700

Bron
Nationaal Trial Register

Verkorte titel
IO-Wrist

Aandoening

Distal radius fractures

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: IlluminOss Medical Inc, East Providence, RI, USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Erasmus MC, Trauma Research Unit, dept. of Surgery - Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam

M.H.J. Verhofstad
P.O. Box 2040, 3000 CA Rotterdam
Rotterdam
The Netherlands
+31-10 7031050

Wetenschappelijk

Erasmus MC, Trauma Research Unit, dept. of Surgery - Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam

M.H.J. Verhofstad
P.O. Box 2040, 3000 CA Rotterdam
Rotterdam
The Netherlands
+31-10 7031050

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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:	01-07-2015
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	29-09-2015
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	NL5233
NTR-old	NTR5457
Ander register	METC Erasmus MC : MEC-2015-283 (METC Erasmus MC)

Resultaten

Samenvatting resultaten
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.