Nonoperative treatment of dorsally dislocated distal radius fractures in adults with an individualized 3D printed brace; a tolerability study in healthy volunteers and patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON45464

Source
ToetsingOnline

Brief title
DRFB-Tolerability

Condition

- Fractures

Synonym
Distal radius fracture; wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,MBrace Medical B.V.

Intervention

Keyword: Brace, Distal radius fracture, Fracture, Treatment

Outcome measures

Primary outcome

Visual Analog Scale (VAS) score for wearing comfort.

Secondary outcome

Fracture redislocation (part 2 only)

Pain (VAS)

Inconvenience during activities of daily living (Katz Index)

Adverse reactions like pain, skin pressure, skin irritation/redness,

sensibility issues, or device-related problems.

Study description

Background summary

Each year, approximately 34,500 adults in The Netherlands sustain a fracture of the distal radius (wrist fracture). Incidence peaks in the elderly. The currently preferred treatment is closed reduction and nonoperative treatment by immobilization in a plaster cast for 4-6 weeks. Surgery is only performed if closed reduction fails or redislocation occurs. Plaster immobilization is inconvenient and interferes with daily activities. More importantly, standard nonoperative treatment often fails; in 40-60% of the fractures, redislocation requires surgery. Surgical treatment is about 9 times more expensive than nonoperative treatment and not without risks. This project aims to develop an innovative nonoperative treatment option. The central idea is to produce a 3D-printed brace for the fractured wrist using a mirrored CT-scan of the contralateral, unfractured wrist as a model. This innovative approach has the advantage that it does not depend on surgery and provides a better and

potentially more durable positioning than the currently applied plaster cast. We expect that redislocation will occur less frequently, so surgery may be avoided. In contrast to a traditional plaster cast, the newly developed brace is water resistant/repellant, lighter, and enables movement of the hand. It enables daily activities and improves independency in the elderly with a wrist fracture. The treatment has been successfully evaluated in an ex vivo model. The clinical implementation will follow a step-wise approach.

Study objective

Part 1 aims to determine the tolerability of the 3D-printed brace when worn by healthy volunteers (50 years of order), performing their normal daily activities.
In part 2, the objective is to determine tolerability of the 3D-printed brace in patients (50 years or older) with an extra-articular distal radius fracture with dorsal displacement, performing their normal daily activities.

Study design

Two consecutive prospective case series.

Intervention

Part 1: Participants will wear the brace continuously for one week.
Part 2: Participants will wear the brace as treatment of the fracture for five weeks.

Study burden and risks

Part 1: A first visit for the scanning procedure of the contralateral wrist and a second visit to apply the brace. Participants will receive a telephone call on day one and three to inquire about pain or other problems. In case of problems, they will visit the outpatient department. If preferred, the investigator may also visit them at home. Skin inspection will take place after removal of the brace (1 week; or earlier if necessary due to problems). On day one, three, and after removal of the brace, participants will be asked to complete a VAS for wearing comfort of the brace and pain during sleep and specific activities.

Part 2: At presentation to the Emergency Department the contralateral wrist is scanned. A second visit at the first working day for the application of the brace. Follow-up data will be collected at one week, two weeks, and after removal of the brace at five weeks (or earlier if necessary due to problems). At the follow-up visits, patients will be asked to complete a VAS for wearing comfort of the brace and pain during sleep and specific activities.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Part 1:
1. Age 50 years or older
2. Healthy volunteer without distal radius fracture
3. No restrictions in activities of daily living prior to enrolment*
4. Signed informed consent by participant;Part 2:
1. Patients (50 years or older) with an acute**, unilateral distal radius fracture with dorsal displacement (AO type 23-A, B, or C) that is acceptably reduced (by simple closed reduction with vertical longitudinal traction)
2. No restrictions in activities of daily living pre-fracture*
3. Signed informed consent by patient;* Participant should exercises complete self-control over urination and defecation, but use of incontinence material is allowed.
** Patients should report to the Emergency Department within 48h post-trauma.

Exclusion criteria

Part 1:
1. Preexisting anatomical deviation of the ipsi- or contralateral wrist
2. Conditions that affect function of the wrist or hand
3. Insufficient comprehension of the Dutch language to understand the study documents
4. Participant unwilling or unable to comply with the study protocol and follow-up visit schedule
5. Known allergy for brace material (PLA or alternative);Part 2:
1. Preexisting anatomical deviation of the ipsi- or contralateral wrist
2. Additional traumatic injuries that affect treatment, rehabilitation, or function of the affected hand
3. Pathological, recurrent, or open fracture
4. Impaired wrist function pre-trauma at either wrist (e.g., arthrosis, rheumatoid disorder, or neurological disorder)
5. Bone disorder that may impair bone healing, excluding osteoporosis
6. Patient unwilling or unable to comply with the treatment protocol and follow-up visit schedule
7. Insufficient comprehension of the Dutch language to understand the study documents
8. Known allergy for brace material (PLA or alternative).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Distal Radius Fracture Brace
Registration:	No

Ethics review

Approved WMO Date:	15-06-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL61002.078.17
Other	Wordt aangevraagd na positief besluit