4D-IRECT Pilot Trial (4 Dimensional - Impairment of posttraumatic forearm Rotation Evaluated with Computed Tomography)

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First, to develop a 4D computer-assisted diagnostic method for estimating the cause of posttraumatic impairment of the forearm. This method is intended to allow differentiation of motion patterns reflecting mutual impingement of radius and ulna from...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON50506

Source
ToetsingOnline

Brief title
4D-IRECT Pilot Trial

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Posttraumatic forearm impairment, restricted forearm rotation at least three months after injury

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Annafonds/NOREF (Netherlands Orthopedic Research and Eduction Foundation)

Intervention

Keyword: 4D-CT scan, Fracture, Kinematics, Radius

Outcome measures

Primary outcome

As an uninjured radius normally rotates +/- 180 degrees around the ulna at the distal radioulnar joint (DRUJ), the aim is to estimate the pattern of restricted motion of the posttraumatic (malunited) radius relative to the ulna, expressed in rotation at the level of the DRUJ. The main endpoint is to study whether we can differentiate between osseous (impinged) versus non-osseous (non-impinged) motion patterns as origin of restricted forearm rotation.

Secondary outcome

Based on the patterns in inter-relational radioulnar motion pattern, the secondary aim is to develop a 4D classification tool for posttraumatic impairment of the forearm and to assess its inter- and intra-observer reliability. Futhermore to assess physiological mechanics of the radioulnar joint and symmetry in motion patterns between two healthy forearms on 4D CT scans.

Study description

Background summary

Radius fractures are associated with posttraumatic sequelae such as symptomatic malunion in 5% (NL:3,400/year) leading to persistent symptoms of pain, loss of function and posttraumatic wrist arthritis. Typical posttraumatic impairment related to malunion involves restricted forearm rotation, which is a pathology of forearm *dynamics*. In the absence of imaging techniques that can visualize the true dynamic behaviour of the forearm in 3D, conventional imaging techniques are used. These conventional techniques, such as radiography (2D), or MRI or CT (3D), take a snapshot in which the cause of the dynamic pathology is rarely seen. The physician therefore has to rely on indirect suggestive findings that coexist with the underlying dynamic restrictions, such as edema or abnormal bone configurations. Dynamic 3D imaging, or 4D imaging (in which time is added as the fourth dimension), has the potential to visualize and quantify forearm motion in 3D. It enables to diagnose if restricted forearm motion is related to bone deformity caused by the malunion, resulting in osseous impingement, or due to rupture or adhesions, resulting in deviating motion patterns without impingement. 4D imaging is therefore expected to make the difference in objectively diagnosing dynamic pathologies!

The proposed study aims at shifting the paradigm of using static 2D/3D musculoskeletal imaging to 4D imaging, and to bring dynamic assessment to the clinic. It enables more specific diagnosis and treatment decision for dynamic pathologies in the complex field of reconstructive surgery of the forearm.

Study objective

First, to develop a 4D computer-assisted diagnostic method for estimating the cause of posttraumatic impairment of the forearm. This method is intended to allow differentiation of motion patterns reflecting mutual impingement of radius and ulna from those caused by soft tissue pathology. Secondly, to develop a classification tool based on the estimated motion patterns and assess its reliability.

Study design

Observational pilot study

Study burden and risks

The radiation exposure is within the category IIa (0,1 - 1 mSv) of the International Commission on Radiological Protection (ICRP), which qualifies as: minor risk. Findings from 4D-CT scans will be used for a better decision making for future patients with posttraumatic impairment of the forearm. While radiation exposure does not allow unlimitedly forearm imaging, due to the absence of organs in limbs, radiation risks are extremely low. As motion is guided voluntary, there is no risk of harm either.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects with posttraumatic forearm impairment:
- Patients with a one-sided posttraumatic impairment of forearm pro- and/or supination
- Patients are over the age of 16 years
- Patients who are willing to give informed consent, Subjects without posttraumatic forearm impairment:
- Subjects are over the age of 16 years and
- Subjects who are willing to give informed consent

Exclusion criteria

Subjects with posttraumatic forearm impairment:
- A history of trauma to both forearms and/or
- Not able to understand or give informed consent and/or
- Pregnancy, Subjects without posttraumatic forearm impairment:
- A history of trauma to one or both forearm(s)
- Not able to understand or give informed consent
- Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2019
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	brilliance CT-scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-03-2018
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL64090.018.17