Clinical Validation of the C-Arm Rotational View (CARV): Study Protocol of a Prospective Randomized Controlled Trial

Published: 11-05-2023
Last updated: 07-04-2024

To assess whether the application of CARV for intra-medullary nailing of tibial shaft fractures results in a more accurate rotationalalignment of the tibia in comparison to conventional (e.g., eyeballing of the surgeon according to current practice...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON53223

Source
ToetsingOnline

Brief title
-

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
Rotational malalignment

Research involving
Human

Sponsors and support

Primary sponsor: Chirurgie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: C-Arm Rotational View (CARV), intramedullary nailing, multi-center, randomized controlled trial., rotational malalignment, tibial shaft fractures

Outcome measures

Primary outcome

The primary endpoint is the degree of rotation of the nailed tibia (with the

contralateral leg as a reference) as measured on a

postoperative CT-scan.

Secondary outcome

-

Study description

Background summary

Rotational malalignment of the tibia occurs in up to 40% of cases after intramedullary-nailing of tibial shaft fractures. The aim of this study is to assess the clinical feasibility of a new introduced standardized intraoperative fluoroscopy protocol coined *C-Arm Rotational View (CARV)* in order to reduce the risk of rotational malalignment during intramedullary-nailing of tibial shaft fractures. The CARV includes predefined fluoroscopy landmark-views of the uninjured side to obtain correct alignment of the injured side with use of the rotation of the C-arm.

Study objective

To assess whether the application of CARV for intra-medullary nailing of tibial shaft fractures results in a more accurate rotational alignment of the tibia in comparison to conventional (e.g., eyeballing of the surgeon according to current practice) alignment of

the tibia during intra-medullary nailing of tibial shaft fractures.

Study design

RCT

Intervention

patients assigned to the intervention group will be treated according to the local guidelines with intramedullary-nailing for a tibial shaft fracture in which alignment of the tibia is guided by the *C-Arm Rotational View* (CARV).

Study burden and risks

The extent of burden and risks for patients participating in the study is considered low, because the operative procedure itself won*t change. Moreover, our pilot study with application of CARV for nailing of tibial shaft fractures (N=5) demonstrated that this technique is feasible, safe and appears to be effective. With the outcome of this study, we intend to present the results at international conferences and publish them in international peer-reviewed journals.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: all consecutive
patients (>=18 years) with an open or closed tibial shaft fracture, who are eligible for intramedullary-nailing, will be
asked to enroll in the study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: age <18 years, fractures not suitable for intramedullary-nailing, medical history of a tibial shaft fracture, bilateral tibial shaft fractures, pathological fractures or when CARV could not be performed due to concomitant fractures.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO Date:	11-05-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT05459038
CCMO	NL84303.042.23