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Bleeker, Nils Jan; Doornberg, Job N.; Ten Duis, Kaj; El Moumni, Mostafa; Jaarsma, Ruurd L.; Ijpma, Frank F.A.

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Clinical validation of the 'C-arm rotational view (CARV)': study protocol of a prospective randomised controlled trial

Nils Jan Bleeker ,[1] Job N Doornberg,[1] Kaj ten Duis,[1] Mostafa El Moumni,[1] Ruurd L Jaarsma,[2] Frank F A IJpma[3]

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[1]Orthopaedic Trauma Surgery, University Medical Centre Groningen, Groningen, The Netherlands
[2]Orthopaedic Trauma Surgery, Flinders Medical Centre, Bedford Park, South Australia, Australia
[3]Orthopaedic Trauma Surgery, Universitair Medisch Centrum Groningen, Groningen, The Netherlands

Correspondence to
Nils Jan Bleeker;
nilsjanbleeker@gmail.com

ABSTRACT

Introduction Rotational malalignment occurs in up to 30% of cases after intramedullary nailing of tibial shaft fractures. The aim of this study is to assess the clinical feasibility of a newly introduced standardised 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.

Methods and analysis This randomised controlled trial will be conducted in a level 1 trauma centre. Adult patients with an open or closed tibial fracture, eligible for intramedullary nailing, will be enrolled in the study. The interventional group will undergo intramedullary nailing guided by the CARV protocol to obtain accurate alignment. The control group is treated according to current clinical practice, in which alignment control of the tibia is based on clinical estimation of the treating surgeon. The primary endpoint is defined as the degree of rotation measured on low-dose postoperative CT scans.

Ethics and dissemination The study protocol will be performed in line with local ethical guidelines and the Declaration of Helsinki. The results of this trial will be disseminated in a peer-reviewed manuscript. Future patients are likely to benefit from this trial as it aims to provide a clinically feasible and easy-to-use standardised fluoroscopy protocol to reduce the risk for rotational malalignment during intramedullary nailing of tibial shaft fractures.

Trial registration number NCT05459038.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Introduction of a new and easy to use standardised fluoroscopy protocol to avoid rotational malalignment during intramedullary nailing of tibia fractures.
⇒ This randomised controlled trial is the first to assess the clinical feasibility of this fluoroscopy protocol coined 'C-arm rotational view (CARV)'.
⇒ Low-dose postoperative standardised CT assessment is used in order to objectify the degree of (mal) rotation of the nailed tibia with the contralateral leg as a reference.

INTRODUCTION

Tibial shaft fractures are common long bone fractures in the field of orthopaedic trauma. In the USA, approximately half a million tibial fractures were registered per year by the National Centre of Health Statistics (NCHS).[1] Intramedullary nailing is the treatment of choice for shaft fractures. However, rotational malalignment defined as a rotation of ≥10° relative to the contralateral side remains a problem with a prevalence up to 30%.[2–10]

From a clinical point of view, there is limited knowledge on how to reduce the risk of rotational malalignment. Clinical estimation and intraoperative judgement of tibial alignment are difficult, often resulting in underestimated alignment errors.[11] This might also be the contributive factor to relatively high incidences reported in literature.[2–10] Low-dose CT assessment is considered the gold standard to objectify rotational malalignment, but it is only performed after surgery when the opportunity for direct revision has passed. Both difficulties in intraoperative clinical judgement of tibial alignment as well as postoperative detection of rotational malalignment when the possibility for direct revision has passed do support the need for an easy-to-use intraoperative fluoroscopy protocol to minimise the risk for rotational malalignment during intramedullary nailing of tibial shaft fractures.

Recently, a standardised protocol named the 'C-arm rotational view (CARV)' was developed in order to improve the accuracy of tibial alignment during intramedullary nailing of tibial shaft fractures. The CARV includes predefined fluoroscopy landmarks of the knee and ankle of the uninjured side

to obtain correct alignment of the tibia at the injured side using the rotation of the C-arm to verify the degree of rotation. Promising preliminary results were found in a recent cadaver and small cohort clinical feasibility study.[12] A prospective trial is needed to determine the performance of CARV in clinical practice. Therefore, a prospective randomised controlled trial is designed to assess the potential clinical benefits of the CARV protocol. The following primary research question was defined: does the CARV protocol reduce the risk of rotational malalignment following intramedullary nailing of tibial shaft fractures?

Primary endpoints

Determine the incidence of rotational malalignment using validated postoperative CT assessment.[9] Rotational malalignment is defined as a rotation ≥10° relative to the contralateral side.[2–10]

MATERIAL AND METHODS

Study setting

To answer the primary research question, a prospective randomised controlled trial is designed. The protocol is structured and written according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist.[13] The study will be conducted in a level 1 trauma centre of the University Medical Centre Groningen, Netherlands.

Patient and public involvement

No patients involved.

Eligibility criteria

All consecutive patients (≥18 years) with a tibial shaft fracture, which is suitable for intramedullary nailing, will be eligible to participate in the study. 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.

Intervention

Patients will undergo intramedullary nailing performed by board-certified orthopaedic trauma surgeons. Fluoroscopy imaging will be performed with use of a C-arm Image Intensifier (II) (GE (General Electric) OEC 9800, Salt Lake City, USA). Patients assigned to the intervention group will be treated according to the local guidelines in which alignment control is guided by the 'C-arm rotational view' (CARV). Patients will be positioned in supine position with the injured leg draped free (figure 1).

First, the fluoroscopy references of the uninjured side are determined by an anteroposterior (AP) view of the knee and mortise view of the ankle (figure 1). The AP knee is defined as exact intersection of the lateral cortex of the proximal tibia through the tip of proximal fibular head.[14] The knee is kept in perfect AP position, while the C-arm is moved towards the ankle. The mortise view, which is defined as an AP view with equal lateral, medial and superior clear spaces, is obtained by rotating the C-arm 20–30° over the ankle, while the leg is remained in its initial neutral position. Both reference images are saved, and the degree of C-arm rotation is recorded (figure 1). Subsequently, the C-arm is moved towards the injured side. Intramedullary nailing will be performed according to the surgeon's routine. When necessary, open reduction of the fracture is allowed and will be left to the discretion of the surgeon. It is part of standard clinical practice, and allowance is important for the generalisability of the findings in this study. Due to randomisation, open fracture reductions will probably be performed equally in both study arms and therefore not cause any selection bias. If the number of open fracture reductions is not equally distributed in both study arms, we will perform correction using a multivariate analysis. First, an identical AP view of the knee is obtained as compared with the contralateral side. Second, a mortise view is obtained by rotating the C-arm in exact opposite gradual position in order to mimic the mortise view of the contralateral ankle (figure 1). Any discrepancies between mortise views of the uninjured and injured side indicate incorrect alignment. Adequate alignment is obtained by rotating the distal part of the tibia until an exact mortise view of the ankle is attained as compared with the reference images. When adequate tibial alignment is obtained according to CARV, definitive locking is performed.

Control group

Patients assigned to the control group will undergo an identical surgical procedure as patients assigned to the interventional group. The only difference with the intervention group is that tibial alignment will be obtained according to present unstandardised clinical standards that range from clinical assessment of the position of the leg to palpating the anteromedial rim of the tibia, fluoroscopy assessment of the cortical width at the fracture site or a combination of techniques.

Outcomes

After surgery, patients in both groups receive low-dose CT assessment in order to objectify the degree of (mal) rotation of the nailed tibia with the contralateral leg as a reference. Low-dose CT assessment is part of the standard of care, and radiation exposure is negligible (0.04–0.06 mGy).[9] A schematic overview of the study is presented in figure 2. The standardised measurement technique, as described by Bleeker *et al*,[9] will be used to measure the degree of (mal)rotation on the postoperative CT images. The interobserver reliability of this measurement technique is 0.95, and the intraobserver reliability is 0.90, both indicating excellent accuracy according to the categorisation of Landis and Koch.[15] To avoid confirmation bias, the CT assessments will be performed by two researchers who are unaware of the treatment allocation, and the

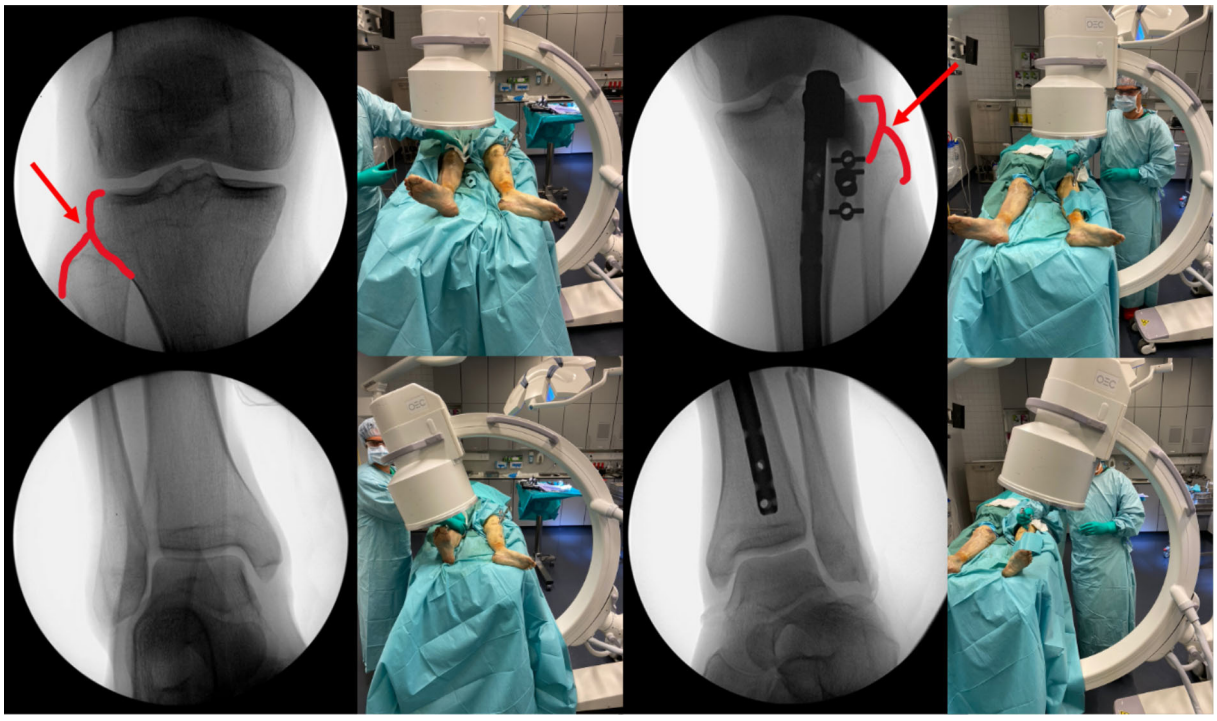

Figure 1 The CARV protocol consists of predefined fluoroscopic landmarks of the injured and uninjured side. The first landmark is the proximal tibiofibular overlap of the uninjured side with the C-arm in neutral position and the knee positioned in perfect AP. The knee is kept in perfect AP position, while the C-arm is moved towards the ankle. The second landmark is the mortise view of the uninjured ankle, obtained by rotating the C-arm. Both reference images are saved, and the degree of C-arm rotation is recorded. The aim of the CARV protocol is to mimic these landmarks on the injured side by first obtaining a perfect AP knee with an equal tibiofibular overlap. The second step is obtaining a mortise view of the ankle by rotating the C-arm in exact opposite direction. Discrepancies in the mortise view indicate rotational malalignment, and adequate alignment can be obtained by rotating the distal part of the tibia until the mortise views of the injured and uninjured side appear to be identical. When adequate tibial alignment is obtained according to CARV, definitive locking is performed.

average of both measurements indicates the degree of (mal)rotation.

Additional data

Baseline data will be collected, including patient characteristics, trauma mechanism, open/closed fracture according to the Gustilo classification,[16] OTA/AO classification,[17] whether open/closed fracture reduction is performed, surgical approach, the gradual position of the C-arm and how surgeons performed rotational control during the operation according to present clinical standards.

Participant timeline

Patients enrolled in the study will undergo intramedullary nailing at T0 of the trial. Patients will undergo postoperative low-dose CT assessment within 2 weeks after surgery. Routine radiographical and functional follow-up using validated patient-reported outcome measures will be performed according to standardised timepoints used in the treating level 1 trauma centre (figure 3). During these outpatient clinic visits, standard radiology imaging of the fractured tibia is performed. The end of study participation is when patients complete the 1-year follow-up (figure 3).

Sample size calculation

The main outcome measure encompasses rotational malalignment. The incidence of rotational malalignment based on data of a historical prospective cohort was 36%.[8] This trial aims to reduce the prevalence from 36% to 15% or less. The power analysis calculated that approximately 132 patients (66 per arm) are needed to decrease the incidence of rotational malalignment to 15% with a power of 80%, CI of 95% and alpha of 0.05. A total of 20% extra patients will be enrolled to recompense for a potential loss to follow-up resulting in a total of 160 patients (80 per arm).

Recruitment and feasibility

Patients presenting at the emergency department of the participating level 1 trauma centre with a tibial shaft fracture eligible for inclusion will be approached by orthopaedic trauma residents or orthopaedic trauma consultants for participation in this trial. Written study information is handed. Once written informed consent is obtained, patients will be randomly assigned to the intervention group or control group.

In total, about 80–100 patients are treated yearly with an intramedullary nail for a tibial shaft fracture in the study hospital. We believe that approximately 80% of the

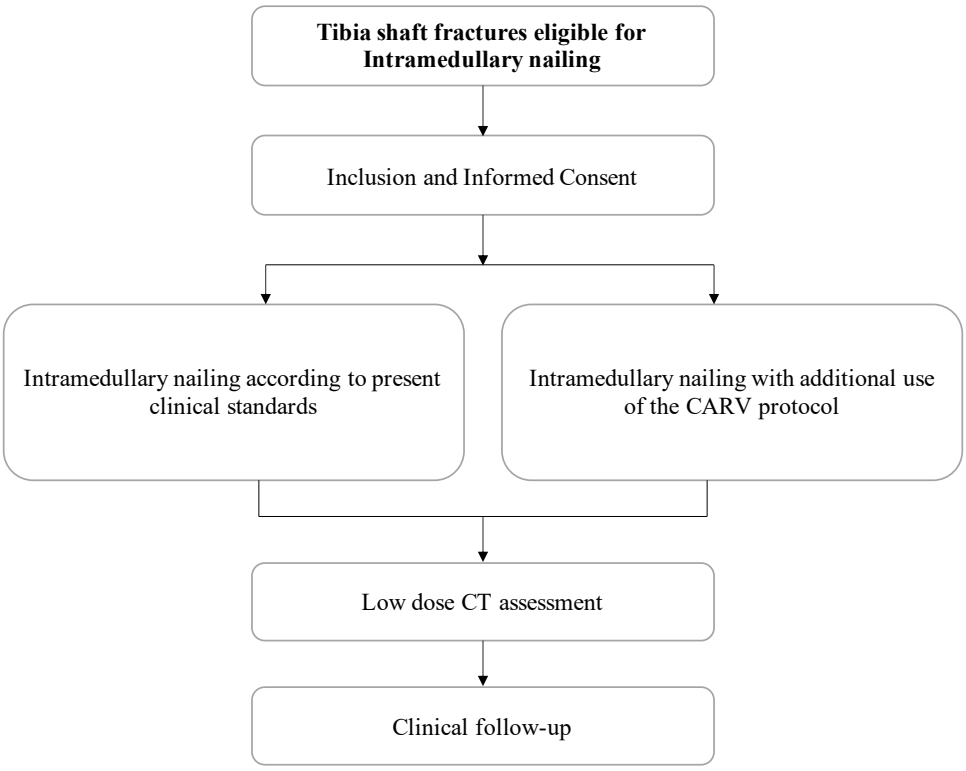

Figure 2 Flow chart of the trial.

patients are willing to participate in the trial. Based on the sample size calculation, the total inclusion period will be approximately 2 years which makes the total duration of the study feasible.

Assignment for interventions

Patients will be randomly assigned to the intervention group (CARV group) or the control group with a 1:1

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	t_0		t_1	t_2	t_3	T_6
			2w	6w	3m	1y
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation	X					
INTERVENTIONS:						
Intervention group: IMN with CARV	X					
Control group: IMN without CARV	X					
ASSESSMENTS:						
Baseline characteristics	X					
Postoperative CT-assessment			X			
Routine radiographic and functional follow-up				X	X	X

Figure 3 Study mapping according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist.

distribution without stratification of patient characteristics using a sealed opaque envelope. Random numbers will be generated by a computer-assisted random number generator. The randomisation process meets the requirements of allocation concealment. Each study hospital does have a local study coordinator who guides and verifies the process of randomisation. Patients will be enrolled in the trial by the researcher of the treating clinician. The trial is blinded for patients by not enlightening them about the allocation for either the interventional or control group. As this trial includes similar surgical procedures in both arms, we feel that this blinding method is justifiable.

Data collection and management

The data will be electronically stored on a secured file according to the local data protection guidelines. Access to the data is only possible by NJB, FIJ or after authorisation of the senior researcher (FIJ). The data is not traceable to an individual participant by anonymisation and encryption. The data will only be used for this research project and will not be used for other research purposes. The quality of data will be ensured by NJB and FIJ, and, in case of uncertainties, a fourth independent researcher will be consulted. The data will all be removed after 15 years of storage.

Statistical analyses

Statistical analyses will be performed using IBM SPSS version 28.0.0.0. Descriptive statistics will be provided for the outcomes of interest. Normal distributed continuous data are presented as means with SD. Not normally distributed data will be presented as median with IQR. In order to determine the rotational differences between both groups, the chi-squared test or Fisher exact test will be used. Correction for confounders such as Gustilo classification,[16] OTA/AO classification,[17] whether open/closed fracture reduction is performed and surgical approach (infrapatellar of suprapatellar) will be performed with a multivariate regression analysis.

Monitoring

Intramedullary nailing is a well-established and often-applied surgical modality for tibia shaft fractures. Besides the potential for recognised health risk related to this treatment modality, the participants in the intervention group will not be exposed to additional health risks in comparison to the control group. We therefore believe that appointment of a data monitor committee (DMC) is of non-contributing value as well as an interim analyses. Potential adverse effects are immediately reported by NJB and FIJ. NJB and FIJ are responsible for reporting the adverse effects to the local ethical committee according to the local guidelines.

ETHICS AND DISSEMINATION

This study protocol will be performed in line with local ethical guidelines and the Declaration of Helsinki. Ethical approval is received from the Medical Ethical Committee of the University Medical Center Groningen, with number 2022/352. The committee will be informed if there are any sufficient changes which may impact the study participants. Informed consent will be obtained by orthopaedic trauma residents or board-certified orthopaedic trauma surgeons, all familiar with the study protocol. The involved clinician is able to provide the necessary information as well as the information provided by the written information forms.

Personal data will be handled strictly confidential, and only NJB and FIJ will have access to the datasets. Participation in this trial is completely voluntary, and participants are able to withdraw from study site at any moment.

Patients allocated to the interventional group are not exposed to additional health risk when compared with patients allocated to the control group. All surgeons participating are board-certified surgeons with ample surgical experience. Patients in both groups undergo identical surgical treatment except for the additional fluoroscopy imaging (four images) which is unlikely to introduce extra potential health-related threats. The exposure of radiation is negligible. Furthermore, participants in both groups receive postoperatively a rotational profile CT, which is part of our current tibia nailing protocol. Exposure to radiation during low-dose CT rotational planning is comparable to a chest X-ray (0.04–0.06 mGy) and, therefore, very minimal.[9] During follow-up, participants in both groups visit our outpatient clinic for routine radiographic follow-up and patient-reported outcome measures at 6 weeks, 3 months and 1 year. There are no extra visits required for patients in the intervention group if compared with the control group (ie, current standard of care).

Future patients with a tibial shaft fracture are likely to benefit from the study outcomes. By performing this randomised controlled trial, we aim to clinically implement the CARV protocol in daily practice and provide an evidence-based method to reduce the risk for rotational malalignment during intramedullary nailing of tibia fractures. The trial aims to start in September 2023.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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ORCID iD

Nils Jan Bleeker http://orcid.org/0000-0002-1221-6058

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