Same level fibular plating versus not plating in distal metaphyseal tibia fractures treated with intramedullary nails: a randomized trial.

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Primary question:I. Does additional fibular plating lower the incidence of malalignment after surgical treatment of distal same level metaphyseal tibia and fibula fractures treated with locked intramedullary nailing?Secondary questions:I. Does...

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

Summary

ID

NL-OMON34420

Source
ToetsingOnline

Brief title
Trans Atlantic Fibula Trial

Condition

- Bone and joint injuries
- Fractures
- Bone and joint therapeutic procedures

Synonym
crural fracture, Fracture of the lower leg

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Geen sponsoring

Intervention

Keyword: Distal metaphyseal tibia, Fibula, Fracture, Intramedullary nail, Plate

Outcome measures

Primary outcome

Tibia alignment in the frontal plane (AP) will be determined by the angle between a line perpendicular to the knee joint line of the tibia and a line perpendicular to the ankle joint line. A positive value will represent varus angulation. Tibia angulation in the sagittal plane (lateral) will be defined as the angle between a line from the anterior 1/5 of the flat subchondral line of the plateaus (tibial joint line at the knee) to a proximal mid-diaphyseal point, and a line from * of the ankle joint line to a distal mid-diaphyseal point. A positive value will represent anterior angulation (procurvatum). Tibia rotation will be administered clinically with the patella forward and measuring the foot rotation with the use of a manual goniometer. Neutral position will be represented by the foot facing upwards perpendicular to the ground. A positive value represents external rotation of the foot. Malalignment will be defined as * 5 degrees deviation from 0 degrees based on the above measurements in any plane. Tibia length will also be measured clinically on both limbs. An independent observer will assess primary outcome.

Secondary outcome

Functional

- Knee and ankle pain (Visual Analogue Scale)

- Walking distance (meters)

- Knee and ankle function (SF-36 short form, Hospital for Special Surgery Knee Service Rating System, American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale)

Bony healing

- Healing of at least three of four cortices of the tibia on biplanar plain radiographs. (Delayed union is defined as lack of any healing on plain radiographs within 3 months, and non-union is defined as lack of progressive healing on plain radiographs over 3 months). Verification by CT scan will be used if there is difficulty in determination of union.

- Extra procedures

> bone grafting,

> exchange intramedullary tibia nailing

> hardware failure (reoperation due to hardware failure will be adjudicated as an outcome only if: 1. The patient complains of pain at the fracture sites or instability when weight bearing, and 2. Radiological evidence of hardware failure: displacement of a fracture, or breakage of the nail, bolts, screws or plate)

Study description

Background summary

Intramedullary nailing has become the standard of care for the majority of displaced midshaft tibial fractures. The use of an intramedullary nail obviates the need for extensive surgical dissection, spares the extraosseous blood supply, and allows the device to function in a load-sharing manner. It results in a stable construct with high union rates, and additional fibular fixation is unnecessary when a combined fracture of the mid tibia and fibula occurs. Intramedullary nails have also been advocated for the treatment of distal metaphyseal tibia fractures. However, because of the lack of interference fit, it can be difficult to reduce and control distal tibia fractures with an intramedullary device, and malalignment rates of 20 to 50% have been reported. Malalignment can impair functional outcome, and may lead to significantly more bodily pain. It is also known that distal tibial malalignment substantially decreases the tibiotalar joint contact area. This leads to inappropriate pressure increase on tibia-talar cartilage and may cause joint degeneration in the long-term.

Some studies of nailing for distal tibia fractures reported that concurrent fibula fixation results in less malalignment of the tibia. Human cadaveric studies suggested that fibular plating increased rotational stability of the tibial fracture treated with a nail, which may reduce the risk of valgus malunion. In addition a retrospective chart and radiographic review showed that adjunctive fibular plating compared to not plating significantly lowered the risk for loss of reduction in the treatment of 72 combined distal third tibia and fibula fractures.
However, it is widely accepted that relative stability with moderate axial movement provides an effective stimulus for periosteal callus formation. An increased potential for delayed healing of the tibia may be seen when the distal fibula is additionally stabilized. Vallier et al. reported that non-union was more common in patients with distal tibia fractures who had concurrent fixation of their fibula fracture. Whorton and Henley found no significant differences in healing rates, incidence of non-union and malalignment, or in the number of required subsequent procedures with patients who did and did not undergo fibular stabilization.

The optimal treatment for combined same level displaced distal tibia and fibula fractures, therefore, remains under debate, and to our knowledge no randomized trials have been reported on additional fibular plating. We designed a randomized controlled trial to answer the following questions: (1) Does additional fibular plating lower the incidence of malalignment after surgical treatment of distal metaphyseal tibia and fibula fractures treated with locked intramedullary nailing? (2) Does fixation of the fibula lead to higher rates of non-union of the distal tibia? We hypothesize that additional fibular plating

would be beneficial to obtain and maintain optimal distal tibia fracture reduction, which may lead to a better functional outcome after 2-years follow-up.

Study objective

Primary question:
I. Does additional fibular plating lower the incidence of malalignment after surgical treatment of distal same level metaphyseal tibia and fibula fractures treated with locked intramedullary nailing?

Secondary questions:
I. Does additional fibular plating give better functional results?
II. Does fixation of the fibula lead to higher rates of non-union of the distal tibia?

Study design

A prospective multicenter open-label parallel randomized controlled clinical trial comparing two strategies of patients treatment with distal same level metaphyseal tibia and fibula fractures, in participating academic medical centers in Canada and Europe.

Randomization
We will use a computer-generated randomization. We will stratify patients according to center and according to the American Society of Anaesthesiologists* (ASA) Physical Status classification. We have chosen to stratify according to center rather than surgeon because: 1. The surgeon to whom a patient is admitted may not be the surgeon who performs the operation, and 2. Since this is a pragmatic study, we are interested in the effectiveness of the intervention under usual circumstances of average surgical skills. We have chosen to stratify according to the ASA class because: 1. It is used worldwide by anaesthesiologists as a preoperative categorization system by patient co morbidities, thus it is readily available preoperatively, and 2. Although it is not a risk stratification system, it will ensure equal representation of patient co-morbidities between the two treatment groups.

We will randomize in random blocks of 4 or 6 in 1:1 allocation ratio. Participating centers will be unaware of block size. After obtaining consent from the patient and checking the eligibility criteria and as close to the operation as possible, the surgeon or the resident will call the randomization service. After entering the center number, patient hospital identification number and ASA class, the computer will provide the caller a treatment allocation (additional fibular plating or not). The central randomization service will ensure concealment of allocation.

Intervention

Operation:
At the start of surgery, the surgeon will follow the treatment allocation. The surgeon will either apply a plate to the distal fibula using a separate incision and then proceed with tibia nailing (index group) or start with tibia nailing (control group):

* In the index group a lateral skin incision and subcutaneous tissue dissection will be used to stabilize the distal fibula fracture with a one/third tubular plate fixated with small fragment screws. Depending on the length and comminution of the fracture site, an appropriate size plate will be chosen by the surgeon. If length of the fibula determination is problematic then the best length and alignment should be chosen for fibular fixation. Time for fibular plating will be recorded.
* In both groups a standard skin incision in line with the central axis of the intramedullary canal will be used for nailing of the tibia. Depending on the anatomy of the patient this incision can be transpatellar, medial, or lateral parapatellar. The incision starts proximally at the distal pole of the patella along the patellar ligament down to the tibial tuberosity. The infrapatellar corpus adiposum can be mobilized laterally and dorsally without opening the synovia. Free access of the nail to the insertion point must be guaranteed.
* A closed reduction or open reduction if the fracture is open (after debridement) will be performed manually by axial traction under image intensification. The length of time to pass the reaming guide wire will be documented. The use of a large distractor may be appropriate in certain circumstances, and will be documented. The reduction can be temporarily fixed with reduction clamps, and will be documented.
* The tibial canal will then be enlarged. A medullary reamer will be used to the desired diameter (ream-to-fit). The appropriate sized intramedullary nail will be inserted over a guide rod, and statically locked with one bolt proximally and two bolts distally.
* A C-arm image intensifier will be used to obtain intra-operative AP and lateral X-rays of the tibia to assess the quality of reduction and position of the locking bolts, and to assess the distal third articular surface for articular extenson of fracture lines.

Study burden and risks

There are no differences in complications for placement of the tibial nail in the treatment groups. As an extra incision will be used for placement of the fibular plate, the risk for infection and lesion of the sensory branch of the superficial peroneal nerve is increased.

Following the randomized treatment, normal and routine care compared to all other patients will be provided. Visits in the fracture clinic at 2 weeks, 6

weeks, 3 months, 6 months, 12 months, and 24 months postoperatively have to be attended. The visits up to 12 months are part of routine care, however, the last visit at 24 months is an addition for the research study. Furthermore, patients will be asked to ccomplete questionnaires at 3 months, 6 months, 12 months and 24 months for trial purposes. These wil take up to 15 minutes each visit.

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

Patients with a fracture distal to the isthmus of the tibial diaphysis and extending through the flare of the distal tibia, without extension to the articular surface, and an ipsilateral fibula fracture at the same level or below (AO/OTA fracture type codes 42 and 43)

Exclusion criteria

Patient is unable to fill out long term outcome forms and/or unable to understand the English language
< 18 years of age
Open tibia fracture Type 3b and 3c according to Gustillo and Anderson
Contralateral tibia fracture at the same time
Previous fracture of the ipsilateral tibia
Delay of surgery more than 7 days from time of injury,
A history of Rheumatoid arthritis, Fibrous dysplasia, Chronic renal failure, Paget*s Disease, or Osteopetrosis.
High risk of death from surgery: ASA Class V

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2011
Enrollment:	21
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2010
Application type:	First submission

Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL32921.099.10