Permissive weight bearing in trauma patients with fracture of the lower extremities

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27998

Source
NTR

Brief title
PWB

Health condition

Trauma, permissive weight bearing, rehabilitation, fractures of the lower extremitiets.

Sponsors and support

Primary sponsor: Maastricht Universitair Medisch Centrum
Adelante Rehabilitation Centre, Hoensbroek
Zuyderland Hospital, Heerlen
University of Aachen Medical Center (Germany)
Source(s) of monetary or material Support: Maastricht Universitair Medisch Centrum
Adelante Rehabilitation Centre, Hoensbroek
Zuyderland Hospital, Heerlen
University of Aachen Medical Center (Germany)

Intervention

Outcome measures

Primary outcome

Main outcome variable:

- ADL (LEFS) with LEFS

Outcome variables for functional outcome:

- Score on LEFS at 0,1, 3, 6, 12, and 26 weeks post-surgery

LEFS: is a questionnaire containing 20 questions about a person’s ability to perform everyday tasks. The LEFS can be used by clinicians as a measure of patients' initial function, ongoing progress and outcome, as well as to set functional goals. The LEFS can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. It can be used to monitor the patient over time and to evaluate the effectiveness of an intervention. The questionnaire consist of 80 points. The lower the score the greater the disability.

Secondary outcome

Secondary outcome variables:

- Function (Brunnstorm Fugl-Meyer)

- Participation (SF-36)

- Reduction in health and society costs

- Improvement in quality of life

- Composite end-point: total complication rate

Outcome variables for functional outcome:

- Score on Brunnstrom Fugl-Meyer at 0,1, 3, 6, 12, and 26 weeks post-surgery

- Score on SF-36 at 0,1, 3, 6, 12, and 26 weeks post-surgery

- Score on EQ-5D-5L at 0,1, 3, 6, 12, and 26 weeks post-surgery

Brunnstrom Fugl-Meyer: is a test that evaluate the degree of synergy formation. The test

consists of 55 test items that can be scored at an ordinal 3 - point scale (0-2 points). The total test consists of an examination of the upper extremity , an examination of the lower extremity and an examination of the balance. For our study we want to use only the examination of the lower extremity. The total score for the motion of the lower extremities consist of 34 points.

SF-36: is a multi-purpose, short-form health survey with only 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. The higher the score the better the participation.

EuroQol: The primary outcome measure for the cost-effectiveness analysis will be better in functional outcome during 6 months of follow-up. Within the cost-utility analysis, outcomes will be measured by means of the standard Dutch version of the EuroQol. This is a self-administered questionnaire, which will be completed at baseline together with the cost questionnaire at the same moments (0,1,3,6,12,26). Both generic quality of life, as well as utilities, will be derived by means of the EQ-5D, which will be administered both by the patients. The EQ-5D is chosen because it is a widely used quality of life instrument (nationally and internationally) and it is recommended by the Dutch guidelines. The EQ-5D contains 5 dimensions of health-related quality of life, namely mobility, self-care, daily activities, pain/discomfort and depression/anxiety. Each dimension can be rated at five levels: no problems to major problems. The 5 dimensions can be summed into a health state. Utility values can be calculated for these health states, using preferences elicited from a general population, the so-called Dutch algorithm. The Dutch algorithm has been established using a general population from the Netherlands. The utilities at the several time points will be are used to compute a Quality Adjusted Life Years (QALY) score by means of the area under the curve method.

Cost-effectiveness:

Economic evaluations compare additional costs and additional outcomes of the permissive weight bearing protocol and AO guidelines (restricted weight bearing). This economic evaluation will involve a combination of a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA). In a CEA effects are presented in clinical outcomes (in our study better primary outcome). We will assess intervention costs, healthcare costs, patient and family costs, and costs outside the health care sector. For this study we will develop a resource use measurement (RUM) instrument especially designed for this group, based on existing questionnaires, which will measure all relevant costs aspects. Costs were calculated by multiplying volumes (resource use) with unit costs. For the units costs we will used the Dutch costing guidelines. Cost prices will be expressed in 2018 euros. If necessary, existing cost-prices will be updated to 2018 using the consumer price index. Following the Dutch

guidelines, an annual discount rate of 1.5% will be applied for the effects, and future costs will be discounted to their present value by a rate of 4%. The Incremental cost-effectiveness ratio (ICER) will be determined on the basis of incremental costs and effects of permissive weight bearing protocol and AO guidelines. The robustness of the ICER will be checked by non-parametric bootstrapping. The bootstrapped cost-effectiveness ratios will be subsequently plotted in a cost-effectiveness plane, in which the vertical line reflects the difference in costs and the horizontal line reflects the difference in effectiveness. The bootstrapped ICERs will also be depicted in a cost-effectiveness acceptability curve showing the probability that permissive weight bearing protocol and AO guidelines is cost-effective using a range of ceiling ratios. Additionally, to demonstrate the robustness of our base-case findings a multi-way sensitivity analyses will be performed. In the sensitivity analysis uncertain factors of assumptions in the base case analysis will recalculated in order to assess whether the assumptions have influenced the incremental cost-effectiveness ratio (ICER), for example by varying cost-prices and volumes between minimum and maximum.

Outcome variables for complication rate:

- Failure of osteosynthesis, defined as loosening or breakage of implants

- Migration of fracture parts, defined as >3 mm articular step-off and/or varus/valgus malalignment >5 degrees

- Infection, defined as (but not limited to) purulent wound drainage, inflammation, erythema, fever, increased white blood cell (WBC) count, increased C-reactive protein (CRP) and/or increased erythrocyte sedimentation rate (ESR), necessitating admission for intravenous antimicrobial treatment and/or revision surgery

- Non-union, defined as no radiographic union achieved after 6 months or no progress in in healing

Complication score

Measurements are taken at 6, 12, and 26 weeks post-surgery.
During scheduled visits to the physician, signs of osteosynthesis failure / infection / non-union / delayed union are recorded into the study database.

Radiographic evaluation by a radiologist blinded for treatment allocation will be done at the same time intervals as the scheduled visits to the physician. Radiographs will be scored for signs of osteosynthesis failure / infection / non-union and migration of fracture parts, and results are recorded into the study database.

Brunnstrom Fugl-Meyer, LEFS, SF-36 and the EuroQol (EQ-5D-5L) are administered by physiotherapist or rehabilitation physician at 0,1, 3, 6, 12, and 26 weeks post-surgery.

Study description

Background summary

The development of surgical fracture care boosted 50 years ago and is improving since, while emphasis on post-surgical care facilitating optimal bone healing and function restoration remains sparse. The positive effects of early weight bearing, both for fracture healing and for maintaining muscle and bone mass, are well known. However, little is known about the association between the amount or timing of weight bearing and bony consolidation or functional recovery. As a result, weight bearing rehabilitation is often cautious and led by existing dogmas, such as the fear for secondary dislocation of the fracture or failure of a mechanical construct. We have developed an early permissive weight bearing post-surgery rehabilitation protocol, where progression of weight bearing is guided by the subjective experience (e.g. pain, weight bearing tolerance) of the patient and therapist, and objective parameters (e.g. temperature, edema, using insoles) are registered. This protocol is based on our clinical experience focused on patient centered rehabilitation and has been validated and implemented in Adelante rehabilitation centre since 2005. Retrospectively we retrieved the medical records and recorded the complications during the time phase the new protocol was used. We found a complication rate of 10 percent. We developed a treatment- and evaluation protocol for permissive weight bearing (PROMETHEUS protocol, see appendix A) to document and to record the weight bearing milestones (e.g. walking with 2 crutches, walking with 2 canes, walking with one cane and walking without any walking aids) in a database. We started practicing the PROMETHEUS protocol method guided by subjective experience of patient and therapist and objective parameters. Hereby, the therapy progression is measured in quality of performing an activity (walking) and not in percentage of bodyweight or in kilogram load bearing. In this proposal we want to compare our new protocol (PROMETHEUS) to the existing AO treatment guidelines in a prospective multi-center trial. This study will be performed in patients with peri- or intra-articular fractures of the pelvis and lower extremity after surgical treatment in which existing protocols do not allow early full weight bearing in the first 6-12 weeks.

Study objective

Hypothesis 1: 1A; Included patients have better early recovery at function level (as measured with the Brunnstrom Fugl-Meyer (BFM) test), 1B; better outcome at activity level (as measured with the Lower Extremity Functional Scale (LEFS)), 1C; better participation (as measured with the SF-36) and 1D; a better quality of life (as measured with the EQ-5D-5L) in the first 6 months post-surgery when they are treated according to the permissive weight bearing protocol compared to patients treated according to standard AO guidelines. It is expected that long-term (1 year) functional outcome will be similar between the treatment groups and will be not the primary aim of this study. We have chosen for these three scales to cover the major outcome levels in the ICF model.18

Hypothesis 2: The permissive weight bearing protocol results is more cost-effective compared to the restricted weight bearing protocol and current guidelines.

Hypothesis 3: The rate of complications (e.g. failure of osteosyntheses, secondary displacement of fracture parts, non-union, infections) is equal or lower in patients who are treated according to the permissive weight bearing protocol compared to patients treated according to standard AO guidelines in the surgery reference.

Study design

The subjects have to complete questionnaires in week 0,1,3,6,12,26. After 6 months the follow-up will be ended.

Intervention

Permissive weight bearing group: Treatment according to the PROMETHEUS protocol (treatment- and evaluation protocol), patients will have an optimal/intensive weight bearing treatment. The protocol contains a number of weight bearing milestones (e.g. walking with 2 crutches, walking with 2 canes, walking with one cane and walking without any walking aids). The treating physiotherapist or physician records the date these milestones are reached in the study database.

Contacts

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Eligibility criteria

Inclusion criteria

• Trauma patients with surgically treated fractures of the lower extremities

• Age > 18

• No additional problem of rheumatic orthopaedic or neurological nature of the lower extremities (i.e. primary coxarthrosis or gonarthrosis)

• Being able to understand the questionnaires and measurement instructions

Exclusion criteria

• Amputation patients (Upper limb, lower limb, feet) and bilateral fractures of the lower extremities.

• Severe non fracture related comorbidity of the lower extremity

• No informed consent

• Additional complaints who influence the measurements

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2017
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion Date:	01-09-2016
Application type:	First submission

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
NTR-new	NL5889
NTR-old	NTR6077
Other	METC Zuyderland : 16-N152

Study results