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

Gepubliceerd: 01-09-2016 Laatst bijgewerkt: 18-08-2022

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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27998

Bron
NTR

Verkorte titel
PWB

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht Universitair Medisch Centrum
Adelante Rehabilitation Centre, Hoensbroek
Zuyderland Hospital, Heerlen
University of Aachen Medical Center (Germany)
Overige ondersteuning: Maastricht Universitair Medisch Centrum
Adelante Rehabilitation Centre, Hoensbroek
Zuyderland Hospital, Heerlen
University of Aachen Medical Center (Germany)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5889
NTR-old	NTR6077
Ander register	METC Zuyderland : 16-N152

Resultaten