Game Ready intermittent cryo- and cyclic compression therapy after fracture repair of the hip: a prospective multicenter study on effects on pain after surgery.

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

Samenvatting

ID

NL-OMON29547

Bron
NTR

Verkorte titel
GRAPES

Aandoening

Hip fractures, postoperative pain, cryotherapy, cyclic compression, cyrocompression

Heup fractures, postoperatieve pijn, cyrotherapie, cyclische compressie, cyrocompressie

Ondersteuning

Primaire sponsor: Spaarneziekenhuis, Hoofddorp
Overige ondersteuning: BMR systems
Achmea zorgverzekeringen, DSW zorgverzekeringen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main parameter of this study is pain 24 hours postoperative measured by the numeric rating scale (NRS).

Measurements will be performed during admission pre- and post GRS-treatment.

The control group will have a single measurement, during the time an intervention patient would normally be treated with the GRS. Before NRS assessment patients will be asked to remain seated or prone in bed for at least 5 minutes. This ensures NRS measurement in rest.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The Game Ready System (GRS) is a device that combines continuous-flow cryotherapy with cyclic compression therapy.

Objective of this study is to evaluate the
effects of the GRS after fracture treatment for hip fracture. Based on a pilot study, the hypothesis is that patients using the GRS after fracture treatment of a hip fracture will have less pain, a smaller drop in hemoglobin levels, less wound discharge and less morphine usage. These factors are associated with a shorter hospital stay. The pilot study was performed with patients undergoing total hip arthroplasty for osteoarthritis. Because of the relative surgical similarity of arthroplasty for osteoarthritis and fracture treatment of a hip fracture these results could easily be applied to the latter. Furthermore patients with a hip fracture are subjected to trauma twice, i.e. the fracture itself with related inflammation and the surgical trauma. Therefore we expect the results to be more beneficial to this category of patients.

Objective: Primary objective of this study is to compare postoperative pain measured

by numeric rating scale (NRS) at 24hrs postoperative between patients treated with the GRS and patients who were not treated with the GRS. Secondary objectives to compare are: NRS at 48 and 72hrs; analgesic/narcotic usage; blood loss (hemoglobin level) and need for blood transfusion; incidence of delirium and use of psychotropic medication; hospital admittance time; location and duration of rehabilitation; functional outcome; patient-reported health outcome; complications and feasibility.

Study design: Open label, multicenter, prospective, randomized controlled, clinical trial.

Study population: Humans with an intra- or extracapsular (per- or subtrochanteric) hip fracture in need for osteosynthesis (i.e. intramedullary nail, dynamic hip screw, cannulated screws) or prosthesis (total hip- or hemiarthroplasty) are studied.

Intervention: Group ‘A’ will be treated with the GRS postoperative, a comparison will be made to group ‘B’ without GRS treatment. Besides the intervention, groups are identical. Routine use of drains and compressive bandages are allowed in both groups.

Main study parameters/endpoints: Postoperative pain is measured with the numeric rating scale. The NRS pain is assessed at fixed hours during admission. NRS scores will be compared at 24hrs, 48hrs, 72hrs and at the outpatient visit.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will have no extra appointments in the outpatient clinic for the study, as outpatient visits will be performed according to hospital protocol. Patients will be asked to fill out a GRS-satisfaction questionnaire at discharge. At the end of the study medical personnel will fill out a similar questionnaire to determine feasibility of the GRS. Intervention patients will have an additional moment of measurements each treatment cycle during admission. Patients treated with the GRS have a minor additional risk of complications; the cryotherapy-related complication-rate is estimated at 0.00225%. We expect GRS treated patients to benefit in regard to pain relief and reduced blood loss.

Doel van het onderzoek

Postoperative pain, further blood loss, onset of delirium and wound discharge are unfavorable factors that can prolong hospital time, delay mobilization and necessitate transfusion. Cryotherapy and pneumatic compression are suggested to minimize these setbacks. A new

device, the Game Ready System (GRS), combines cryotherapy and cyclic compression therapy.
Based on results from a pilot study we expect patients to have less pain, less postoperative blood loss, less wound discharge and possibly a shorter hospital stay when treated with the GRS.

Onderzoeksopzet

- NRS: at 24hrs, 48hrs, and 72hrs and at outpatient visit between 6 and 8 weeks

- Analgesics: assessed after the last treatments at 72hrs

- Postoperative blood loss: preoperative, 24hrs and 72hrs

- Transfusion incidence: throughout hospital stay

- Delirium incidence and psychotropic medication: daily, throughout hospital stay

- Location, duration of rehabilitation: at discharge and at outpatient visit

- Timed up and Go test: after last treatment or before discharge and at outpatient visit

- De Morton Mobility Index: at outpatient visit

- SF-12 and EQ-5D: at outpatient visit

- Patient satisfaction: before discharge

- Feasibility: after discharge of last patient

- Complications: at discharge and at outpatient visit

Onderzoeksproduct en/of interventie

This study intervenes with the postoperative treatment after fracture treatment for hip fracture. The intervention group ‘A’ consists of adding the Game Ready System (GRS). The Game Ready System (CoolSystems: Alameda, California) simultaneously delivers both adjustable continuous-flow cold therapy and intermittent compression through a portable control unit filled with ice and with water and anatomically designed wraps. The GRS has four pressure settings: no pressure, low pressure (5-15 mmHg), medium pressure (5-50 mmHg) and high pressure (5-75 mmHg). Temperature can also be

adjusted and is indicated by one, two or three snowflakes. If tolerated, we will use the coldest setting which is 3 snowflakes corresponding with a minimal temperature of 4.0°C. During the first 72hrs postoperative, patients will be treated between 10 – 12 times in total. We will start with the lowest pressure setting and increase the setting stepwise on a daily basis. Cold or pressure settings are reduced if requested by the patient.

Contactpersonen

Publiek

Bonairestraat 85-2

N.C. Leegwater
Amsterdam 1058 XE
The Netherlands

Wetenschappelijk

Bonairestraat 85-2

N.C. Leegwater
Amsterdam 1058 XE
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with intra- or extracapsular hip fracture in need for total hip-, hemiarthroplasty, intramedullary nailing, a dynamic hip screw or canullated screws.

- Older than 18 years

- Able and willing to give informed consent prior to treatment and randomization. If the patient is unable to give informed consent, proxy consent must be obtained.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Fractures at multiple foci

2. Open fracture/skin lacerations/open wounds

3. Acetabular fracture

4. (Suspicion of) concomitant malignancy

5. BMI >40

6. Preoperative osteosynthesis/prosthesis materials in situ in the ipsilateral leg above knee level

7. Unable or unwilling to give informed consent by proxy

8. Morphine allergy or dependence

9. ≥ ASA 4

10. Cold hemoglobinuria/cryoglobulinemia

11. Morbus Raynaud

12. Central neuromuscular disorder

13. Absent distal pulsations in the injured extremity

14. History of deep vein thrombosis

15. Patient delay >24 hrs

16. NYHA ≥ 3

17. Incapacitated individuals (IQCODE score ≥ 4.6)

18. Postoperative hemodynamic instability

19. Peroperative use of local anesthetics (LIA) or femoral blocks

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2014
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-08-2013

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	NL3980
NTR-old	NTR4152
Ander register	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Leegwater NC, Willems JH, Brohet R, Nolte PA. Cryocompression therapy after elective arthroplasty of the hip. Hip Int. 2012 Sep-Oct;22(5):527-33 (PMID: 23112075)