

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29547

Source

NTR

Brief title

GRAPES

Health condition

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

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

Sponsors and support

Primary sponsor: Spaarneziekenhuis, Hoofddorp

Source(s) of monetary or material Support: BMR systems

Achmea zorgverzekeringen, DSW zorgverzekeringen

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- NRS at 48hrs, 72hrs and at outpatient visit
- All used analgesics: acetaminophen, NSAID's and morphine.

All administered forms of morphine are recalculated to a single form.

- Postoperative blood loss. Blood samples will be taken in which hemoglobin concentrations will be measured.
- Transfusion incidence and number of transfused units.

Including autologous drain reinfusion.

- Incidence, severity and duration of delirium and use of psychotropic medication
- Hospital admittance time: starting count at A&E arrival time.
- Location and duration of rehabilitation

- Functional outcome
- Patient-reported health outcome
 - o Timed up and Go test
 - o De Morton Mobility Index
 - o SF-12 questionnaire
 - o EQ-5D questionnaire
- Patient satisfaction
- Feasibility of the Game Ready system
- Complications
 - o Cryotherapy related
 - o General

Study description

Background summary

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.

Study objective

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.

Study design

- 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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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. \geq 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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014

Enrollment: 160
Type: Actual

Ethics review

Positive opinion
Date: 27-08-2013
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	NL3980
NTR-old	NTR4152
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

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)