Game Ready continuous-flow cryo- and cyclic compression therapy after fracture treament of the hip: a prospective multicenter, open-label, multicenter, randomized, controlled, clinical trial on postoperative effects on pain.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON41653

Source
ToetsingOnline

Brief title
GRAPES

Condition

- Procedural related injuries and complications NEC
- Fractures
- Bone and joint therapeutic procedures

Synonym
broken hip, hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: DSW;Achmea

Intervention

Keyword: cryocompression, functional outcome, hip fracture, pain

Outcome measures

Primary outcome

Primairy outcome is 11-point numeric rating scale (NRS painscore) at 24 hours

after surgery.

Secondary outcome

- 48 hours postoperative NRS painscore

- 72 hours postoperative NRS painscore

- Total morphine consumption; measured by recalculating all the administered

morphine to one form (e.g. Oramorph)

- Postoperative bloodloss measured by hemoglobin values preoperative, at day 1

and day 3

- The necessity for transfusion of erythrocyte concentrate

- Admission time (in hours)

- Functional outcome at 6 weeks measured by the Timed Up and Go Test and the

Morton Mobility Index

- Self-assessed health outcome (EQ-5D en SF-12)

- Complications (DVT, infection, early aseptic loosening of the prosthesis)

- User-friendliness of the GRS

- Incidence of delirium and use of psychotropic medication

- Rehabilitation location (home/rehabilitation clinic) and duration

- Thermodynamic properties of applied therapy (optional)

Study description

Background summary

Because of the aging population hip fracture incidence is steadily rising and will continue to rise for the years to come.
Hip fracture surgery is typically situated in the acute setting. Because of this, patients already lost blood due to fracture-site bleeding and possibly to soft tissue damage. This will result in a preoperative drop in hemoglobin. Postoperative pain, further blood loss and wound discharge are unfavorable factors that can delay recovery. There is evidence that cryo- and compressiontherapy can minimize these setbacks. However these two modalities have not been administered simultaneously. A relatively new system called the Game Ready System combines these two treatments. The system is being used in sports for quite some time with good results. Because of this, we conducted a pilot study to evaluate the postoperative effects of the Game Ready after total hip arthroplasty for end-stage osteoarthritis. Treated patients appeared to have less pain, less postoperative blood loss and a trend was observed towards less morphine consumption. Because hip fracture surgery and total hip arthroplasty are similar types of surgery we expect these positive results also to be applicable to the former. Since patients who fractured their hip already lost a substantial amount of blood and a related inflammation has already occurred the results might even be more beneficial.

Study objective

The goal of the study is whether to establish if application of combined cyrocompression therapy directly postoperative after hip fracture surgery results in a significant reduction in painperception en whether this reduces the morfine consumption. Secondly postoperative blood loss, delirium incidence and functional outcome is compared between groups. Furthermore an estimation is made about the penetration of applied therapy.

Study design

This is an open-label, parallel, multicenter prospective randomized clinical trial where patients will be included in the ER of 5 different hospitals (7 departments). After surgery patients will be randomized. GR treatment will

commence six hours after surgery up till 4 times daily during the first 72 hours postoperatively.
After this treatment ends and patients will be followed up until 6-weeks in the outpatient clinic.
On this regular outpatient clinic visit both the functional and self-assessed health outcomes are tested. Complications will be assessed aswel.

Optionally patients admitted to the Spaarne Gasthuis can choose to participate in additional measurements with which an estimation can be made of the penetration of applied cryotherapy.

Intervention

The only intervention consists of the postoperative application of the Game Ready treatment.
This is a commercially available machine which combines cyro- and compression therapy into one.
The machine has 4 pressure settings; no pressure, low pressure (5-15 mmHg), medium pressure (5-50 mmHg) and high pressure (5-75 mmHg)
The temperature can also be adjusted between 4,0°C and 10,0°C with 3 settings.
We will use the lowest temperature setting corresponding with a minimum temperature of 4,0°C, if tolerated by patients.
GR treatment will commence 6 hours after surgery. Initially we will start with the lowest pressure setting. The following treatments the pressure will be increased to maximum, if tolerated by patients.
In total patients will be treated 4 times daily in 72 hours.

Study burden and risks

Given the fact that ice-water is used temperature can never fall below 0 °C. Because of this, it is theoretically unlikely to suffer frost injury. This was not observed in our pilot study, literature reports a complication risk of 0.0025%.
Patients allocated to the intervention group will be asked to fill in the satisfaction questionnaire which the control group will not have to fill in.
During treatment intervention patients are required to stay in bed. However control patients are required to do the same around the moment of measurements for standardization purposes.
The questionnaires and functional tests which have to be completed will be administered during the regular outpatient clinic visits, no additional appointments will be made.
The intervention group might benefit from the application of the GR and have less pain, blood loss, morfine consumption and delirium incidence.
In summary we conclude that this study will have a minimum risk and burden for patients in the control- and intervention group alike. The intervention group is expected to benefit from treatment.

Willing patients will receive 3 skin thermometers on their legs (2 ipsilateral, 1 contralateral). The measurements will take place overnight (start at 21:30 h), the burden for the patients is that they have 3 lines in situ during their sleep. For the duration of the measurements it is important that they stay in bed (minimal muscle activity), if a toilet visit for instance is needed the lines can be unplugged. Measurements take 5 hours, if the patient is asleep after this time he/she will not be awakened but the thermometers will be removed at the patients convenience.

Contacts

Public
Spaarne Ziekenhuis

Spaarnepoort 1
Hoofddorp 2134 TM
NL
Scientific
Spaarne Ziekenhuis

Spaarnepoort 1
Hoofddorp 2134 TM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 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 GRS treatment and randomization.

Exclusion criteria

1) Fractures at multiple loci
2) Open fracture/skin lacerations/open wounds
3) Acetabular fracture
4) (Suspicion of) concomitant malignancy
5) BMI >40
6) Preoperative osteosynthesis 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/cryoglobulinaemia
11) Morbus Raynaud
12) Central neuromuscular disorder
13) Absent distal pulsations in the injured extremity (vascular impairment)
14) Active deep vein thrombosis or suspected pulmonary embolism
15) Patient delay >24 hrs
16) NYHA * 3
17) Only if the clinician has doubts about the cognitive state of the subject can the IQCODE be administered, if the IQCODE score * 4.6 is will the subject be excluded
18) Postoperative hemodynamic instability
19) Use of local anaesthetics (LIA) or long-acting femoral blocks

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2014
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	Game Ready System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-09-2014
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	13-10-2015
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL45657.094.14