Effectiveness of blood flow restriction after anterior cruciate ligament reconstruction

No registrations found.

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

Summary

ID

NL-OMON20815

Source
Nationaal Trial Register

Brief title
Best FRiend-trial

Health condition

ACL-rupture

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Quadriceps and hamstring strength 8 and 14 weeks after BPTB ACL reconstruction.

Secondary outcome

Leg muscle size, physical function, patient satisfaction, patient confidence, knee laxity, knee pain and knee effusion at 8-, 14-, 26-, 39- and 52- weeks after BPRB ACL reconstruction. Furthermore, completion of revalidation and adverse events will be documented.

Study description

Background summary

Rationale:
Heavy load resistance (HLR) training using external loads of 70% repetition maximum (RM) is recommended to stimulate muscle hypertrophy and strength. Low-load blood flow restriction (BFR) therapy using external loads of 30% RM is becoming increasingly popular in anterior cruciate ligament (ACL) injury rehabilitation. The advantage of low-load BFR therapy is that strength training can be started immediately after surgery. However, the effect of low-load BFR therapy after bone-patellar tendon-bone (BPTB) ACL reconstruction is still unknown.

Objective:
The purpose of this study is to evaluate the effect of low-load BFR therapy on quadriceps and hamstring strength 8-, 14-, 26-, 39- and 52-weeks after BPTB ACL reconstruction compared to conventional HLR training.

Study design:
A prospective randomized placebo-controlled trial.

Study population:
Patients who need surgery after ACL trauma who will be operated for primary BPTB ACL reconstruction will be included. Patients at increased risk of adverse reactions of BFR application will be excluded: diabetes, sickle cell anemia, severe hypertension, renal compromise, venous thromboembolism, extremity infection, lymphadenectomy and cancer.

Intervention:
Postoperative low-load BFR therapy using external loads of 30% RM.
Comparison:
Postoperative conventional HLR training using external loads of 70% RM and placebo BFR therapy.
Main study parameters/endpoints:
Primary outcomes are: quadriceps and hamstring strength 8-, 14-, 26-, 39- and 52-weeks after BPTB ACL reconstruction. Secondary outcomes are: leg muscle size, physical function, patient satisfaction, patient confidence, knee laxity, knee pain and knee effusion. Furthermore, completion of revalidation and adverse events will be documented.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness BFR therapy has been suggested to increase the risk of adverse cardiovascular or cerebrovascular events in diseases such as hypertension, heart failure and peripheral artery. No other side-effects of BFR therapy have been reported.

Study objective

Low-load blood flow restriction therapy has beneficial effects on postoperative quadriceps and hamstrings atrophy/strength, at 8 and 14 weeks after bone-patellar tendon-bone anterior cruciate ligament reconstruction, compared to standard care resistance training and placebo blood flow restriction therapy. We hypothesize that the difference in quadriceps and hamstrings atrophy/strength wil reduce over time.

Study design

2 weeks preoperative
- Informed consent
- Randomization
- Quadriceps and hamstrings strength tests: Isokinetic quadriceps (seated leg extension) and hamstring (standing leg curl) strength will be measured on KINEO LEG PRO (Globus, Codogne, TV, Italy)
- Leg muscle size: 15cm proximally and distally from the knee joint using a flexible tape measure. The average of three consecutive measurements will be documented
- Physical function: Physical functioning will be measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS) (0 to 100, 100 being the best outcome)
- Patient satisfaction: 0 to 10 scale (0=dissatisfied, 10=satisfied)
- Patient confidence: Anterior cruciate ligament return to sport after injury scale (ACL-RSI) (0 to 100, 100 being the best outcome)

Operation:
- operative details (eg. operation time)

8-, 14-, 26-, 39- and 52 weeks postoperative
- Knee laxity: With participants laying in supine position and 30° and 90° of knee flexion, laxity will be measured and graded as normal (0-2mm), mild (2-5mm), moderate (6-10mm) or severe (>10mm)
- Knee pain: Visual analog scale (VAS) (0 no pain while 10 is the maximum pain)
- Knee effusion: Knee effusion grading will be based on the stroke test (zero, trace, 1+, 2+ and 3+). The examiner strokes upwards from the medial joint line towards the suprapatellar pouch. A downward stroke on the distal lateral thigh from the suprapatellar pouch towards the lateral joint line is performed and a wave of fluid will be observed at the medial knee.
- Serious Adverse Events:
A serious adverse event (SAE):
• Is any untoward medical occurrence or effect that at any dose results in death;
• Is life threatening (at the time of the event);
• Requires hospitalisation or prolongation of existing inpatients' hospitalisation;
• Results in persistent or significant disability or incapacity;
• Is a new event of the trial likely to affect the safety of the subjects, such as an unexpected outcome of an adverse reaction, lack of efficacy of an Investigational Medicinal Product (IMP used for the treatment of a life threatening disease, major safety finding from a newly completed animal study, etc.
All SAEs will be reported to the accredited METC that approved the protocol, according to the

requirements of that METC.

Intervention

Low-load blood flow restriction therapy (30% 1-RM)
Low-load sham blood flow restriction therapy
Heavy load resistance training (70% 1-RM)

Contacts

Public
Zuyderland Medisch Centrum
Martijn Schotanus

06-52377871
Scientific
Zuyderland Medisch Centrum
Martijn Schotanus

06-52377871

Eligibility criteria

Inclusion criteria

Bone-patella tendon-bone anterior cruciate ligament reconstruction
Post operative revalidation at "Kniecentrum Plus"

Exclusion criteria

Known diabetes mellitus
Known sickle cell anemia
Known hypertension
Known renal disfunction
Known deep vein thrombosis
Any infection of the extremities
Known lymphadenectomy
Known carcinoma

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-05-2020
Enrollment:	35
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	22-04-2020
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	NL8546
Other	METC ZUYD : METCZ20190147

Study results