

# Effectiveness of blood flow restriction after anterior cruciate ligament reconstruction

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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...

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20815

### Bron

NTR

### Verkorte titel

Best FRIend-trial

### Aandoening

ACL-rupture

### Ondersteuning

**Primaire sponsor:** None

**Overige ondersteuning:** none

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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

## Toelichting onderzoek

### Achtergrond van het onderzoek

#### 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.

### Doel van het onderzoek

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 will reduce over time.

## Onderzoeksopzet

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.

## Onderzoeksproduct en/of interventie

Low-load blood flow restriction therapy (30% 1-RM)

Low-load sham blood flow restriction therapy

Heavy load resistance training (70% 1-RM)

## Contactpersonen

### Publiek

Zuyderland Medisch Centrum

Martijn Schotanus

06-52377871

### Wetenschappelijk

Zuyderland Medisch Centrum

Martijn Schotanus

06-52377871

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Bone-patella tendon-bone anterior cruciate ligament reconstruction

Post operative revalidation at "Kniecentrum Plus"

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

## Onderzoeksopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blinding:        | Dubbelblind           |
| Controle:        | Geneesmiddel          |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 04-05-2020           |
| Aantal proefpersonen:   | 35                   |
| Type:                   | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nee

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 22-04-2020       |
| 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        | NL8546                    |
| Ander register | METC ZUYD : METCZ20190147 |

## Resultaten