# Effectiveness of blood flow restriction training after bone-patellar tendon-bone anterior cruciate ligament reconstruction: a randomized placebo-controlled trial

Published: 06-04-2020
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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 placebo BFR therapy and conventional HLR training.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Tendon, ligament and cartilage disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON49262

**Source**
ToetsingOnline

**Brief title**
Effectiveness of blood flow restriction training after ACL

### Condition

- Tendon, ligament and cartilage disorders

**Synonym**
Anterior cruciate ligament (ACL) reconstruction

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum
**Source(s) of monetary or material Support:** het is standaard zorg bij desbetreffende fysiotherapie

## Intervention

**Keyword:** anterior cruciate ligament reconstruction, blood flow restriction training, bone-patellar tendon-bone

## Outcome measures

### Primary outcome

Primary outcomes are: quadriceps and hamstring strength 8-, 14-, 26-, 39- and

52-weeks after BPTB ACL reconstruction.

### Secondary outcome

Secondary outcomes are leg muscle size, physical function, patient

satisfaction, patient confidence, knee laxity, knee pain and knee effusion 8-,

14-, 26-, 39- and 52-weeks after BPTB ACL reconstruction. Furthermore,

completion of revalidation and adverse events will be documented.

# Study description

### Background summary

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.

### Study 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 placebo BFR therapy and conventional HLR training.

### Study design

A prospective randomized placebo-controlled trial.

### Study burden and risks

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.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)
Adolescents (16-17 years)

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

### Inclusion criteria

Patients who underwent primary bone-patellar tendon-bone anterior cruciate ligament reconstruction

### Exclusion criteria

Patients known with
• diabetes
• sickle cell anemia
• severe hypertension
• renal compromise
• venous thromboembolism
• extremity infection
• lymphadenectomy
• cancer

## Study design

### Design

| | |
|---|---|
| Study phase: | 3 |
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-07-2020 |
| Enrollment: | 35 |

| | |
|---|---|
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 06-04-2020 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 12-08-2020 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |

## 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 | NL71800.096.19 |

## Study results

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|---|---|
| Date completed: | 30-03-2023 |
| Actual enrolment: | 35 |