MRI-BASED GRAFT MATURITY AFTER BLOOD FLOW RESTRICTION TRAINING IN BONE-PATELLAR TENDON-BONE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION: A RANDOMIZED CONTROLLED STUDY

Published: 21-12-2023
Last updated: 02-12-2024

Primary objective: The effect of LL-BFRT on MRI-based graft maturity after BPTB ACL reconstruction compared to HLRT.Secondary objectives: The effect of LL-BFRT on donor-site morbidity, range of motion, knee stability, PROMs, muscle strength, safe...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON56498

Source
ToetsingOnline

Brief title
TimeToMature

Condition

- Tendon, ligament and cartilage disorders

Synonym
knee injury, ruptured cruciate ligament

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Dr. C.J. Vaillant-Fonds

Intervention

Keyword: ACL reconstruction, Blood flow restriction training, graft maturation

Outcome measures

Primary outcome

The effect of LL-BFRT on MRI-based graft maturity three months after BPTB ACL reconstruction compared to HLRT.

Secondary outcome

The effect of LL-BFRT on donor-site morbidity, range of motion, knee stability, PROMs, muscle strength, safe return to pre-injury level of sport and patient satisfaction compared to HLRT. Furthermore, feasibility and safety of rehabilitation (LL-BFRT or HLRT) will be assessed.

Study description

Background summary

The bone-patellar tendon-bone (BPTB) and hamstring tendon autograft are commonly used in anterior cruciate ligament (ACL) reconstruction [1]. Although, the BPTB has superior stability compared to the hamstring tendon autograft, some studies have found that it has more donor-site morbidity [2, 3]. After ACL reconstruction, the autograft changes from a tendinous to a ligamentous intra-articular appearance also known as graft maturation [4]. Previous studies have demonstrated three characteristic stages of graft maturation: an early healing phase, followed by a phase of proliferation and finally a phase of ligamentization [4]. During these phases of graft maturation, changes in cellularity, vascularity and extracellular matrix transform characteristics into properties of an intact ACL [5].

Range of motion, knee stability, patient-reported outcome measurements (PROMs), muscle strength and patient satisfaction have traditionally been used to evaluate the success of ACL reconstruction and timing of safe return to pre-injury level of sport [6]. However, these outcome measurements lack the sensitivity to determine graft maturity [7]. Graft maturity assessed as graft signal intensity (signal-to-noise quotient, SNQ) on magnetic resonance imaging (MRI) is correlated with strength and biomechanical properties of the reconstructed ACL [8]. Therefore, graft maturity may better assess timing of safe return to pre-injury level of sport.
In ACL reconstruction rehabilitation, there are concerns that the gold standard heavy-load resistance training (HLRT) may have detrimental effects on ACL graft maturation [9]. Therefore, low-load blood flow restriction training (LL-BFRT) has been suggested as an alternative to HLRT [9]. As LL-BFRT is an increasingly popular method for the rehabilitation after an ACL reconstruction, it is important to evaluate the value of this treatment [11]. Previous studies showed promising results of LL-BFRT on muscle strength in healthy participants [10]. The main objective of this study is to evaluate the effect of LL-BFRT on MRI-based graft maturity after BPTB ACL reconstruction compared to HLRT. The secondary objectives are to investigate the effect of LL-BFRT on donor-site morbidity, range of motion, knee stability, PROMs, muscle strength and safe return to pre-injury level of sport. Furthermore, feasibility and safety of rehabilitation will be assessed.

Study objective

Primary objective: The effect of LL-BFRT on MRI-based graft maturity after BPTB ACL reconstruction compared to HLRT.
Secondary objectives: The effect of LL-BFRT on donor-site morbidity, range of motion, knee stability, PROMs, muscle strength, safe return to pre-injury level of sport and patient satisfaction compared to HLRT. Furthermore, feasibility and safety of rehabilitation (LL-BFRT or HLRT) will be assessed.

Study design

A randomized controlled study. This study will be conducted in the Netherlands and aims for completion within 48 months.

Intervention

Patients in the LL-BFRT group will perform four sets (30, 15, 15 and 15 repetitions, respectively) of unilateral leg press, seated leg extension, deadlift and squat exercises with 30s inter-set rest periods throughout a 0-90° range of motion at 30% one-repetition maximum [9, 15]. BFR will be achieved using an automatic personalized tourniquet system (PTS) (MAD-UP, Angers, France) designed to automatically calculate limb occlusion pressure (Figure 1). Limb occlusion pressure is defined as the minimum pressure required for blood

flow occlusion, with clinically acceptable accuracy and high reliability. Limb occlusion pressure will be calculated in the position the exercise will be performed. BFR is comprised of a dual-purpose easy-fit variable contour nylon cuff (11.5x86 cm, 5mm thick) connected by airtight hose tubing and automatically regulates pressure within acceptable limits. A limb occlusion pressure of 80% with BFR will be applied during each exercise with 60s deflation between different exercises.

5.2 Comparison
Patients in the HLRT group will perform 3x10 reps (30s inter-set rest) of unilateral leg press, seated leg extension, deadlift and squat exercises exercise throughout a 0-90° range of motion with incremental increase in external-load up to 70% of patients* one-repetition maximum [15].

Study burden and risks

LL-BFRT promotes muscle hypertrophy and strength. In addition, LL-BFRT can reduce pain and effusion which results in improved physical function. LL-BFRT has been suggested to increase the risk of adverse cardiovascular or cerebrovascular events in diseases such as severe hypertension and sickle cell anemia. Therefore, patients at risk of adverse reactions of BFR application will be excluded. No other side-effects of BFR training have been reported.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients who will undergo primary BPTB reconstruction at Zuyderland Medical Center and rehabilitation at Knie-Heup centrum Plus.

Exclusion criteria

The exclusion criteria are: venous thromboembolism, sickle cell anemia, severe hypertension, contra-indication for accelerated rehabilitation, contra-indication for MRI scan or not willing/able to participate.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2024

Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-09-2024
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
ClinicalTrials.gov	NCT05972876
CCMO	NL83376.096.22