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Effect of blood-flow restriction on platelet-rich plasma composition

Submission date 15/04/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/04/2024	**Overall study status** Completed	
Last Edited 13/08/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Blood-flow restriction therapy is an exercise in which tourniquets are used on the upper and/or lower limbs to partially restrict the muscle's blood flow. This stimulates a stress environment in the muscle that, combined with low-load exercise, has been linked with similar strength and hypertrophy (muscle growth) gains to traditional weight training. The tourniquets restrict 80% of the blood flow for about 5 minutes, using around 30% of the load regularly used for the exercise.
The molecules IL-6 and IGF-1 are typically released during exercise and are related to the muscle changes resulting from exercise/training (increased strength, endurance, and volume). Scientific studies have demonstrated that different types of exercise (aerobic, weights, etc) result in different changes in these molecules. The aim of this study is to determine how blood-flow restriction therapy could change the levels of IL-6 and IGF-1 in plasma (the fluid part of the blood). The changes of these molecules in the plasma caused by the blood-flow restriction therapy could be translated in the future to treat some diseases or injuries with substances produced by our bodies.

Who can participate?
Healthy athletic men between 18 and 40 years old with no musculoskeletal conditions that would interfere with exercise

What does the study involve?
1. Personal data collection
2. A short questionnaire to determine eligibility
3. A blood collection before exercise
4. Performing load-low bilateral knee extensions with or without blood-flow restriction therapy. The decision to do it under blood-flow restriction will be randomly allocated on the day of the study
5. Blood collection 10, 20 and 30 minutes after exercise
6. Analysis of the blood samples
Participation in the study will take only 2 hours. The investigators will cover the participation

costs and laboratory analysis. All participants will be monitored for 72 hours after to record adverse events and health care coverage. All study data will be protected and only accessible to the investigators for 5 years before destruction.

What are the possible benefits and risks of participating?
Patients will benefit from the study by learning and experiencing an exciting exercise modality that can impact their current sporting activities and training and updated blood tests for health screening purposes.
Blood-flow restriction therapy has been deemed safe under medical supervision. The risks are comparable to those of traditional exercise. However, there are few reports of adverse events such as pain or discomfort during exercise, delayed onset muscle soreness, increased heartbeat, increased blood pressure, numbness, bruising, fainting, clot formation, and muscle injury. These risks are negligible following the current standards.

Where is the study run from?
Centro Profesional Las Mercedes, Clínica Santa Sofía, and Laboratorio Avilab in Caracas (Venezuela)

When is the study starting and how long is it expected to run for?
January 2024 to January 2025

Who is funding the study?
The International Society of Arthroscopy, Knee Surgery, and Orthopaedic Sports Medicine (ISAKOS) (USA)

Who is the main contact?
1. Dr Theodorakys Marín, theodorakys.marin@ucv.ve
2. Dra Janet Fermín

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
001-2024 version

Study information

Scientific Title
Blood flow restriction enhanced platelet-rich plasma: a pilot

Acronym
BFR-PRP

Study objectives
The present study aims to assess platelet-rich plasma (PRP) changes in platelet and leukocyte count, IGF-1, and IL-6 concentration after bilateral low-load knee extensions under blood flow restriction (BFR). The hypothesis is that bilateral low-load knee extensions under BFR will increase platelet and leukocyte count, IGF-1, and IL-6 in PRP prepared after the exercise bout.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/02/2024, Comité de Bioética del Grupo Médico Vargas - Clínica Santa Sofía (Av. Ppal. Santa Sofía, Edif. Clínica Santa Sofía, Caracas, 1061, Venezuela; +58 (0)2123355030; sociedadmedicasantasofia@gmail.com), ref: S/N

Study design
Randomized controlled trial

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
GP practice, Hospital, Laboratory

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Platelet-rich plasma changes after bilateral low-load knee extensions under blood-flow restriction in the athletic population

Interventions
Before the intervention, participants will have a pre-exercise peripheral vein catheterization, blood sample draw, and PRP preparation for baseline measurements. Each participant will undergo standard venipuncture in the antecubital fossa by a single phlebotomist under sterile conditions for a total blood draw of 15 ml in a BD vacutainer and undergo a single centrifugation at 1500 rpm for 5 minutes. The plasma portion and buffy coat will be separated from the red blood cells, and samples will be sent to the laboratory and divided into two aliquots, one for cell counts (automated cell counter), the other for IGF-1 and IL-6 immunoassays analysis within 6 hours.

The participant will then perform the low-load BFR protocol. The low-load bilateral knee extensions under BFR (using tourniquets at the proximal end of both thighs) will follow the standard protocol of four sets consisting of 30-15-15-15 repetitions, with 30-second rest intervals at 80% of limb occlusive pressure (calculated using arteria pedis ultrasound) and 30% of 1-RM load (using Holten diagram). Individuals will be randomly assigned to the intervention or control groups (performing the low-load knee extension protocol without BFR) at recruitment (1:1).

A staff physician will monitor the entire exercise protocol and recovery period for safety and adverse events. Once the exercise protocol is completed, participants will be allowed a recovery period (including rest, walking if desired, and fluid intake) before undergoing the consecutive blood draw. The maximum recovery permitted time will be 5 minutes. The subsequent blood draws and PRP processing will be performed identically to the first at 10, 20, and 30 minutes post-intervention.

Intervention Type
Other

Primary outcome measure
IGF-1 and IL-6 plasmatic concentrations measured by immunoassay analysis at baseline, 10, 20 and 30 minutes after bilateral knee extensions under blood-flow restriction therapy

Secondary outcome measures
Platelet and leukocyte plasmatic concentrations measured with an automated cell counter at baseline, 10, 20 and 30 minutes after bilateral knee extensions under blood-flow restriction therapy

Overall study start date
01/01/2024

Completion date
01/01/2025

Eligibility

Key inclusion criteria

1. Healthy individuals undergoing routine health screening
2. Aged between 18 and 40 years
3. No musculoskeletal conditions that would interfere with exercise

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Male

Target number of participants
22

Key exclusion criteria
1. Systemic inflammatory diseases
2. Cardiovascular risk factors
3. Any blood dyscrasia
4. Tegner Activity scale score <5
5. Under nonsteroidal anti-inflammatory drugs and aspirin treatment within 1 week before testing
6. Previously performed exercises on the testing day

Date of first enrolment
12/05/2024

Date of final enrolment
12/08/2024

Locations

Countries of recruitment
Venezuela

Study participating centre
Laboratorios Avilab
6ta Transversal de Altamira con Avenida San Juan Bosco, Edificio Clínica El Avila, Anexo A, Piso 1
Caracas
Venezuela
1060

Study participating centre
Clínica Santa Sofía
Av. Ppal. Santa Sofía, Edif. Clínica Santa Sofía
Caracas
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Study participating centre
Centro Médico Profesional Las Mercedes
Av. Ppal. de Las Mercedes con calle Mucuchíes, piso 3, consultorio 37.
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Sponsor information

Organisation
International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine

Sponsor details
San Ramon (GeoNames ID 5392593)
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Sponsor type
Other

Website
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ROR
https://ror.org/02427qx15

Funder(s)

Funder type
Other

Funder Name
International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine

Alternative Name(s)
International Society of Arthroscopy, Knee Surgery & Orthopaedic Sports Medicine, Intl Society of Arthroscopy Knee Surgery and Orthopaedic Sports Med, INT'L SOC OF ARTHROSCOPY KNEE SURG, ISAKOS Society, ISAKOS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in the Journal of ISAKOS and the 2025 ISAKOS Congress

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study will be published as a supplement to the publication of the results.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/04/2024	No	Yes
Participant information sheet	in Spanish		24/04/2024	No	Yes
Other files	Informed consent form (in Spanish)		26/04/2024	No	No
Protocol file			26/04/2024	No	No
Statistical Analysis Plan			13/08/2024	No	No