

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of beetroot extract supplementation coinciding with resistance training on maximum concentric peak torque and power of the quadriceps and hamstring muscles in semi-professional male athletes after anterior cruciate ligament surgery

Protocol summary

Study aim

Determining the effect of 4 weeks of beetroot extract supplement along with resistance training on body composition, maximum concentric torque, and power in quadriceps and hamstring muscles at 60, 90 and 120 degrees per second after ACL surgery

Design

Non-randomized, parallel, unblinded, phase 2 clinical trial on 46 male athletes

Settings and conduct

This study will be conducted in the field of post ACL reconstruction surgery rehabilitation on 46 male athletes (18 to 35 years old) who underwent ACL reconstruction surgery (after 90 days) in a sports medicine center in Mashhad. All subjects (intervention and control groups) will follow a similar exercise protocol of 90-minute strength training 3 sessions per week for 4 weeks (overall 12 sessions). The intervention group will also consume 250 ml beetroot extract (40% ADI for nitrate), two hours before exercise in 2 non-consecutive sessions. A list of nitrate rich foods will be given to subjects to reduce dietary nitrate intake. Maximum concentric torque and quadriceps and hamstring power by isokinetic device and body composition by body composition analyzer will be assessed at baseline and 48 hours after the last exercise session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male athletes who have undergone ACL reconstruction (allograft technique) 90 days prior to inclusion in the study. No entry conditions: Allergy to beetroot, bilateral injuries to the knee and other tissues and ligaments of the knee, including intra-articular fractures, consuming beetroot extract less than 2 times a week during the study, failure to follow the diet and exercise program based on research protocol

Intervention groups

Intervention group: 250 cc beetroot extract (40% ADI of nitrate) with resistance exercise
Control group: Resistance exercise

Main outcome variables

Strength and power of quadriceps and hamstrings, body composition

General information

Reason for update

Failure to update previous revision

Acronym

IRCT registration information

IRCT registration number: **IRCT20210217050393N2**

Registration date: **2021-07-26, 1400/05/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-21, 1401/07/29**

Update count: **2**

Registration date

2021-07-26, 1400/05/04

Registrant information

Name

REZA REZVANI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2418

Email address

rezvanir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of beetroot extract supplementation coinciding with resistance training on maximum concentric peak torque and power of the quadriceps and hamstring muscles in semi-professional male athletes after anterior cruciate ligament surgery

Public title

Evaluating the effect of beetroot extract supplementation coinciding with resistance training in rehabilitation of athletes with anterior cruciate ligament rupture

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Male semi-professional athletes who play in provincial teams in the fields of football, futsal, volleyball and basketball Undergoing ACL reconstructing surgery using allograft technique 90 days have passed since the ACL reconstruction surgery Adhere to the same protocol, which includes 40 sessions of physiotherapy with 60 sessions of exercise therapy, from the day of surgery to the end of 90 days for all subjects Willingness to participate in research Age between 18 and 35 years old

Exclusion criteria:

Disease including: diabetes, kidney stones, gallstones, cancer and other serious diseases Taking any medication or performing extra exercise compared to the research protocol Using oral and injectable nutritional supplements before and after the research period Consumption of any herbal medicine Allergy to beetroot Smoking Alcohol consumption History of performing any surgery on the operated limb Bilateral knee injuries Damage to other tissues and ligaments of the knee, including intra-articular fractures

Age

From 18 years old to 35 years old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

This study is a non-randomized parallel clinical trial with control group

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad university of medical sciences

Street address

Mashhad university of medical sciences, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.109

Health conditions studied**1****Description of health condition studied**

Anterior cruciate ligament rehabilitation

ICD-10 code

M62.50

ICD-10 code description

Muscle wasting and atrophy, not elsewhere classified, unspecified site

Primary outcomes**1****Description**

Maximum concentric torque of quadriceps and hamstring at 60 degree per second

Timepoint

Baseline and 48 hours after the last exercise session (4 weeks)

Method of measurement

Isokinetic device at 60 degree per second

2**Description**

Maximum concentric torque of quadriceps and hamstring at 90 degree per second

Timepoint

Baseline and 48 hours after the last exercise session (4 weeks)

Method of measurement

Isokinetic device at 90 degree per second

3

Description

Maximum concentric torque of quadriceps and hamstring at 120 degree per second

Timepoint

Baseline and 48 hours after the last exercise session (4 weeks)

Method of measurement

Isokinetic device at 120 degree per second

4

Description

Power of quadriceps and hamstring muscles at 60 degree per second

Timepoint

Baseline and 48 hours after the last exercise session (4 weeks)

Method of measurement

Isokinetic device at 60 degree per second

5

Description

Power of quadriceps and hamstring muscles at 90 degree per second

Timepoint

Baseline and 48 hours after the last exercise session (4 weeks)

Method of measurement

Isokinetic device at 90 degree per second

6

Description

Power of quadriceps and hamstring muscles at 120 degree per second

Timepoint

Baseline and 48 hours after the last exercise session (4 weeks)

Method of measurement

Isokinetic device at 120 degree per second

Secondary outcomes

1

Description

body composition

Timepoint

Baseline and 48 hours after the last exercise session (4 weeks)

Method of measurement

Body analyzer device

Intervention groups

1

Description

Intervention group: 250 cc beetroot extract containing 40% ADI nitrate based on body weight will be given to the athlete two hours before exercise in two non-consecutive sessions. The duration of the intervention will be 4 weeks, which includes 12 sessions of resistance training and 8 servings of beetroot supplement. Sachets containing extract powder will be prepared by the Mashhad School of Pharmacy

Category

Rehabilitation

2

Description

Control group: Resistance training for 4 weeks including 12 resistance training sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehregan Pars Physiotherapy Center

Full name of responsible person

Mohammad Hossein Khabaz Kababi

Street address

Mehregan Pars building, Next to the Shahid Aghdaei 1St, Vakilabad 35 Ave, Vakilabad Blvd

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ahoseleh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad university of medical sciences, Azadi square

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tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Reza Rezvani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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School of Medicine, Mashhad University of Medical Sciences. Azadi Square, Campus of University, Mashhad, Iran Postal Code: 9177948564

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code

No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available