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Effect of thigh muscle cooling on standing balance in healthy young males

Submission date	Recruitment status	[ ] Prospectively registered
25/12/2016	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
06/01/2017	Completed	[X] Results
Last Edited	Condition category	[ ] Individual participant data
15/01/2018	Musculoskeletal Diseases	

Plain English summary of protocol
Background and study aims:
The use of cryotherapy (cooling therapy) in the form of ice packs, gel packs, and ice immersion are frequently used to treat minor muscle injuries. Although ice is known to be effective in decreasing pain and feeling, its effect on balance has received comparatively little attention. In addition to the various benefits of cryotherapy, reduced performance scores have been reported immediately after treatment. The role of quadriceps (thigh) and hamstring (calf) muscles for maintaining standing balance is well established, but the effect of cooling of these muscles on standing balance has not been reported previously. The aim of this study therefore is to compare the effect cooling the quadriceps and hamstring muscles on standing balance in healthy men.

Who can participate?
Healthy men aged between 20 and 30.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group are asked to lie down on their back and have a cool pack placed on their thigh for 20 minutes. Those in the second group are asked to lie down on their front and have a cool pack placed on their calf for 20 minutes. Those in the third group rest for 20 minutes and do not receive any cooling. At the start of the study and after the cooling period (20 minutes), participants in all groups stand on a special plate which measures their balance.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Rehabilitation Research Chair, King Saud University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
December 2014 to March 2016

Who is funding the study?
Rehabilitation Research Chair, King Saud University (Saudi Arabia)

Who is the main contact?
Mr Shahnawaz Anwer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of quadriceps and hamstrings muscle cooling on standing balance in healthy young males

Study objectives
1. The effects of quadriceps or hamstring muscles cooling on standing balance are significant in healthy individuals
2. The differences in the effects of quadriceps and hamstring muscles cooling on standing balance are significant in healthy individuals

Ethics approval required

Old ethics approval format

Ethics approval(s)
CAMS Research ethics committee, King Saud University, Saudi Arabia, 08/01/2015, ref: CAMS 21 /3536

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Balance following muscle cooling

Interventions
Participants are randomised to one of three groups by lottery method.

Quadriceps cooling (QC) group: Participants are asked to lie down in a supine position and a cold pack (gel pack, temperature -60 C to -120 C) is placed on the anterior thigh (from apex of patella to mid-thigh) of the both limbs for 20 minutes.

Hamstrings cooling (HC) group: Participants are asked to lie down in a prone position and a cold pack (gel pack, temperature -60 C to -120 C) is placed on the posterior thigh (from base of the popliteal fossa to mid-thigh) of the both limbs for 20 minutes.

Control (no cooling) group: Participants rest without any intervention.

At baseline and post-cooling/rest (20 minutes) participants have their sway velocity assessed using a force plate.

Intervention Type
Device

Primary outcome measure
Sway velocity (degree/sec) for the Unilateral Stance (US) is tested on a force plate (NeuroCom Balance Master®) at baseline and immediately after the cooling protocol.

Secondary outcome measures
No secondary outcome measures

Overall study start date
12/12/2014

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Male
2. Age 20-30 years
3. Healthy

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
30

Key exclusion criteria
1. History of recent previous knee injury
2. Sensory deficits in lower extremity
3. History of previous recent lower extremity surgery

Date of first enrolment
10/02/2015

Date of final enrolment
20/12/2015

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Rehabilitation Research Chair
College of Applied Medical Sciences, King Saud University
Building Number 24 G095/1

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Sponsor information

Organisation
King Saud University

Sponsor details
Building Number 24
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Sponsor type
University/education

Website
http://ksu.edu.sa/en/

ROR
https://ror.org/02f81g417

Funder(s)

Funder type
University/education

Funder Name
Rehabilitation Research Chair, King Saud University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Shahnawaz Anwer (sanwer@ksu.edu.sa)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No