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Recovery implications of cooling after ACL surgery - Pilot study

Submission date
04/12/2015

Recruitment status
No longer recruiting

Registration date
18/01/2016

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The anterior cruciate ligament (ACL) is a tough band of tissue in the middle of the knee, preventing the shin bone (tibia) from sliding out in front of the thigh bone (femur). It is one of the four main ligaments within the knee, and the most common to be injured. An ACL rupture is a common knee injury, which often occurs during high-intensity sports such as football or basketball. They happen when the ACL in the knee is over-stretched and becomes torn (ruptured). This causes the knee joint to become very unstable and can make some types of movement very difficult. There are number of different types of surgery used to treat ACL ruptures, however they often lead to swelling, pain and even the muscles wasting away (atrophy). Applying cold (such as an ice pack or cold-compress) to an injury is commonly used in the treatment of sports injuries, as it has been shown to relieve pain and swelling and even speed up recovery. Up to now, there has been little research comparing the effectiveness of menthol (alcohol) containing liquids to the conventional method of cooling with ice. The additional benefit of menthol-containing liquids, which are applied in the form of wet bandages, may include an intensified sensation of cold. The aim of this study is to compare the effectiveness of a traditional cold-compress to the application of a methanol-containing liquid at relieving pain, swelling and preventing muscle atrophy.

Who can participate?
Adults who have experienced an ACL rupture in the past 8 weeks.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group are given the “cool down Fix Aid” cooling product, which consists of a normal bandage, wetted with a menthol-containing liquid (cool down Ice Fluid), which is wrapped around the knee. From day 1 to 30 (while the patient is in hosptial), the bandage is applied three times a day for 120 minutes, and then from day 31-90 (which the patient is seen as an outpatient for rehabilitation therapy), the bandage is applied twice a day for 120 minutes. Those in the second group are given a “HotCold Pack” to use, which after being kept in the freezer for two hours, is attached to the knee with a bandage. From day 1 to 30, the pack is applied three times a day for 20 minutes, and then from day 31-90, the pack is applied twice a day for 20 minutes. Those in the third group do not have any cooling treatment for the 90 days of the study. Throughout the study, participants

complete a number of questionnaires and physical tests in order to monitor their pain levels, range of motion and monitor any muscle wasting.

What are the possible benefits and risks of participating?
Participants may benefit from improved rehabilitation due to the cooling techniques used. There are no expected risks of taking part in this study.

Where is the study run from?
Orthopedics St. Gallen (Switzerland)

When is the study starting and how long is it expected to run for?
December 2015 to June 2016

Who is funding the study?
Cool Down AG (Switzerland)

Who is the main contact?
Mr Daniel Engelhard
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015_01

Study information

Scientific Title
Recovery implications of cooling interventions after Anterior Cruciate Ligament (ACL) surgery (ACOOL) - Pilot study

Acronym
ACOOL

Study objectives
The complementary use of a cool down ice fluid in the rehabilitation phase after ACL surgery improves the rehabilitation of patients compared to the conventional use of ice packs or no cooling and, thus, reduces the amount of atrophy observed in the m. vastus medialis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of St. Gallen, 03/12/2015, ref: EKSG 15/160

Study design
Prospective single-centre un-blinded three-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Acute anterior cruciate ligament disruption

Interventions
Participants are randomly allocated to one of three groups.

Experimental intervention group: Participants use the "cool down Fix Aid" cooling product, which consists of a standardized bandage wetted with a menthol-containing liquid (cool down Ice Fluid) for immediate use (cool down Fix Aid, Bandage 1.5 metres unstretched). The Bandage will be wrapped around the knee (10 centimeters distal until 10 centimeters proximal from the knee). It will be fixed with cool down Underwrap. The maximum duration of cooling with cool

down Ice Fluid is 120 minutes. In the hospital phase (day 1-30) the ColdHot Pack is applied 3 times a day for 20 minutes, and in the outpatient rehabilitation phase (day 31-90) the ColdHot Pack is applied twice a day for 20 minutes,

Standard intervention group: Participants use the "ColdHot Pack" for the duration of the study. Following preparation in the freezer for 2 hours, the ColdHot Pack is applied over a thin fleece covering the skin, and held in place with a short stretch compression bandage. The maximum duration of cooling with ColdHot Pack is 20 minutes. In the hospital phase (day 1-30) the cool down Fix Aid is applied 3 times a day for 120 minutes, and in the outpatient rehabilitation phase (day 31-90) the cool down Fix Aid is applied twice a day for 120 minutes,

Control group: Participants do not receive any cooling treatment for the duration of the study period (both hospital and outpatient rehabilitation phases). The physiotherapy is standardized during the hospital phase (day 1 to 3) two times a day and the during the rehabilitation phase (day 4 to 90) three times a week.

Intervention Type
Device

Primary outcome measure
Cross-sectional measurement of vastus medialis measured in millimeters on day 1, 30, 60 and 90.

Secondary outcome measures
1. Skin temperature is measured in degree Celsius by using an iButton on day 1 tand 3
2. Knee swelling and Range of Motion (ROM) are measured in circumference in centimeters and degrees by using a tape measure and a handheld goniometer on day 8, 15, 22, 29, 36, 43, 50, 57, 64, 71, 78 and 85
3. Consumption of analgesic medication is measured using an questionnaire on day 7 and 30
4. Pain perception and comfort feeling is measured using an questionnaire with Numerical Ratingscale (NRS) and Thermal comfort scale on day 1 and 30
5. Muscle strength is measured in maximum torque value of knee extension and flexion, which is expressed in newton metre by using an isokinetic dynamometer (Biodex System) on baseline and day 90

Overall study start date
01/12/2015

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Acute anterior cruciate ligament disruption (8 weeks post-traumatic)
2. Aged between 18 and 60 years
3. With and without concomitant ligament injuries

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Chronic leg pain
2. Hypersensitivity, cold tolerance, peripheral neuropathy, diabetes mellitus
3. Eczema or rashes
4. Allergy to menthol and/or ethanol

Date of first enrolment
01/12/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
Switzerland

Study participating centre
Orthopädie ST. Gallen
Rosenbergstrasse 42b
St. Gallen
Switzerland
9000

Sponsor information

Organisation
Cool Down AG

Sponsor details
Andhauserstrasse 64
Berg
Switzerland
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Sponsor type
Other

ROR
https://ror.org/01ecxzf56

Funder(s)

Funder type
Industry

Funder Name
Cool Down AG

Results and Publications

Publication and dissemination plan
Planned publication of study results in a peer reviewed journal.

Intention to publish date
31/10/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/06/2019	14/01/2022	Yes	No