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The use of PRICE (Protection, Rest, Ice, Compression and Elevation) in the management of acute soft tissue injury

Submission date	Recruitment status	[X] Prospectively registered
24/10/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2010	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sponsor: PRF/05/2

Study information

Scientific Title

Acronym
PRICE

Study objectives
The aim of the project is to further enhance the evidence for the management of acute soft tissue injuries.

The specific objective is to compare the effectiveness of an intermittent icing protocol when applied with and without early mobilisation in treating subjects with acute ankle sprains.

Please note that as of 10/12/2007 the anticipated duration of this trial was updated to 01/09/2007 to 01/07/2008. The previous anticipated start and end dates of this trial were as follows:
Anticipated start date: 01/01/2007
Anticipated end date: 01/06/2008

The secondary outcome measures have also been updated, and changes are entered under the date 10/12/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Full ethics approval received on the 18th August 2007 from the Office for Research Ethics Committees in Northern Ireland (ORECNI).

Study design
A double blind, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Subjects with acute ankle sprains will be recruited

Interventions
Group one: Intermittent ice only (10 minutes ice/10 minutes rest /10 minutes ice).
Group two: Intermittent ice (10 minutes ice/10 minutes rest /10 minutes ice) plus early mobilisation (patients will be encouraged to perform a range of mobility and flexibility exercises during icing, and for 10 minutes after icing).

The mode of cryotherapy will be standardised across groups, consisting of melting iced water (0° C) in a standard sized pack. All groups will receive standardised physiotherapy management, and advice regarding general mobility and proprioceptive exercises.

This trial has joint sponsorship with University of Ulster, Jordanstown and Royal Victoria Hospitals Trust. For details of University of Ulster, see Sponsor section.

Details of Royal Victoria Hospitals Trust (UK):
Frances Burns
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Royal Victoria Hospital
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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure will be subjective ankle function, assessed using Binkleys lower extremity functional scale. This scale has excellent test retest reliability, and good construct validity. This will be recorded at baseline, one, two, three, four and six weeks post injury.

Secondary outcome measures
Current secondary outcome measures as of 10/12/2007:
1. Ultrasound imaging of the injured ankle. Subjective and objective measurement of swelling, ligament damage. This will be recorded at baseline, one, two, three, four and six weeks post injury
2. Pain at rest and on activity will be assessed using a 10 cm visual analogue scale
3. Swelling will be measured using a figure of eight method. All measurements will be undertaken using one-quarter inch wide plastic tape following a standard written protocol and valid tool for measuring the girth, of both healthy and oedematous ankles. This will be recorded at baseline, one, two, three, four and six weeks post injury
4. Muscle strength measured on the KinCom 500H Isokinetic Dynamometer, according to a standard written protocol. This will be measured at twelve weeks post injury

Previous secondary outcome measures:
1. Ultrasound imaging of the injured ankle. Subjective and objective measurement of swelling, ligament damage. This will be recorded at baseline, one, two, three, four and six weeks post injury
2. Pain at rest and on activity will be assessed using a 10 cm visual analogue scale

3. Swelling will be measured using a figure of eight method. All measurements will be undertaken using one-quarter inch wide plastic tape following a standard written protocol and valid tool for measuring the girth, of both healthy and oedematous ankles. This will be recorded at baseline, one, two, three, four and six weeks post injury
4. Eversion strength will be measured on the Biodex 3 dynamometer, according to a standard written protocol. This will be measured at six weeks post injury

Overall study start date
01/09/2007

Completion date
01/07/2008

Eligibility

Key inclusion criteria
Subjects with an acute (less than 72 hours) grade one or two acute ankle injury, between 16 and 65 years of age will be considered for inclusion in the study.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
N = 106

Key exclusion criteria
They will not be admitted to the study if any of the following criteria are present:
1. Non English speaking
2. Learning disabilities or mental illness
3. Under the influence of drugs or alcohol
4. A bony ankle injury (diagnosed by Ottawa ankle rules or X-Ray) or ankle ligament rupture
5. Multiple injuries
6. Injuries more than 72 hours old
7. Insufficient address for follow up
8. Unwillingness to return for follow up
9. Contraindication for cryotherapy

Date of first enrolment
01/09/2007

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Ulster
Newtownabbey
United Kingdom
BT37 OQB

Sponsor information

Organisation
University of Ulster, Jordanstown (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.ulster.ac.uk/campus/jordanstown/

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Research organisation

Funder Name
Physiotherapy Research Foundation (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	01/08/2006		Yes	No
Results article	results	10/05/2010		Yes	No