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The effect of ankle tape on joint position sense after local muscle fatigue

Submission date	Recruitment status	[_] Prospectively registered
10/12/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/12/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/01/2018	Other	

Plain English summary of protocol

Background and study aims
An ankle sprain is an injury to the tough bands of tissue (ligaments) that surround and connect the bones of the leg to the foot. During physical activity, the ankle may twist inward as a result of sudden or unexpected movement. Fatigue and joint position sense are two elements that affect ankle sprain. Joint position sense measures the individual's ability to perceive the position of a joint. Fatigue impairs joint position sense, which makes the incidence of ankle sprain high. Ankle tape is widely used to prevent ankle sprain, but is still not approved if ankle tape improve joint position sense after fatigue. The aim of this study is to examine if ankle tape can affect the joint position of the ankle after muscle fatigue.

Who can participate?
Healthy adults aged 16 to 40 years old.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group do not receive any ankle tape. Those in the second group receive ankle tape. Participants are measured before and after muscle fatigue to assess the impact of the ankle tape.

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

Where is the study run from?
University Hospital Marburg (Germany)

When is the study starting and how long is it expected to run for?
December 2011 to December 2013

Who is funding the study?
University Clinic Marburg (Germany)

Who is the main contact?
1. Mr Akram Jahjah (Scientific)
2. Dr El-Zayat Bilal Farouk (Scientific)

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DRKS00013590

Study information

Scientific Title
The effect of ankle tape on joint position sense after local muscle fatigue: a randomized controlled trial

Study objectives
Does the tape affect the joint position sense on the ankle after muscle fatigue in healthy subjects?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Philipps-University Marburg (Germany), 17/04/2012, ref: study 23\12

Study design
Interventional single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Healthy subjects

Interventions
Participants are randomly distributed into control (without ankle tape) and intervention (with ankle tape) groups In both groups, joint position sense was measured before and after local muscle fatigue. For participants in intervention group tape is applied just before the first test and it was removed after second test. Preventive taping for injuries to the lateral aspect of the ankle joint is used and applied according to Macdonald’s method. Fatigue protocol was applied by Biodex System Isokinetic Dynamometer 3. The local load applied to the ankle joint consisted of 30 consecutive maximal concentric/concentric contractions of the ankle evertors and invertors in the range of motion ROM (30° of eversion and 30° of inversion) at an angular velocity of 120°/s. Immediately after the fatigue protocol, joint position sense testing is initiated using the same methods as in the testing before fatigue, to minimize the effects related to recovery from fatigue.

Intervention Type
Supplement

Primary outcome measure
1. Active joint position sense (Joint position sense in Absolute Error (AE) and variable Error (VE)) is measured using the Biodex 3 at baseline

2. Passive joint position sense is measured using the Biodex 3 at baseline
3. Active joint position sense is measured using Biodex 3 after fatigue
4. Passive joint position sense is measured using Biodex 3 after fatigue

Secondary outcome measures
1. Fatigue Index (Fatigue Index = (initial peak torque - final peak torque) / initial peak torque * 100) is measured using Biodex 3 after first test
2. Work is measured using Biodex 3 after first test
3. Work at first third measured using Biodex 3 after first test
4. Work at last third measured using Biodex 3 after first test

Overall study start date
01/12/2011

Completion date
01/12/2013

Eligibility

Key inclusion criteria
Healthy volunteers between 16 and 40 years of age

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
34

Key exclusion criteria
1. History of lower extremity injuries
2. Neurologic deficits
3. Rheumatologic disease
4. Hypermobility

Date of first enrolment
01/05/2012

Date of final enrolment
30/08/2012

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Marburg
Apartment for Physiotherapy
Baldingerstrasse
Marburg
Germany
35033

Sponsor information

Organisation
Universitätsklinikum Gießen und Marburg, Standort Marburg

Sponsor details
Baldingerstraße
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Germany
35033

Sponsor type
University/education

Website
www.ukgm.de

ROR
https://ror.org/032nzv584

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Clinic Marburg

Results and Publications

Publication and dissemination plan

Planned publication in BMC Musculoskeletal Disorders. Study protocol is available in German.

Intention to publish date
31/01/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Akram Jahjah at akramjahjah@yahoo.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/01/2018		Yes	No