Assessment of function of Gastrocnemius and Soleus during walking in able bodied adults and selective electrical stimulation of the 2 muscles.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON29753

Source
ToetsingOnline

Brief title
Triceps Surae function in normal gait

Condition

- Other condition

Synonym
Able Bodied subjects, Normal subjects

Health condition

Normal Subjects

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Erasmus Student Exchange Programme

Intervention

Keyword: Electrical Stimulation, Gait, Gastrocnemius, Soleus

Outcome measures

Primary outcome

Kinetic and kinematic parameters such as joint rotations, moments and powers along with EMG will be primary parameters.

The data will be analysed using the clinical manager for kinetic and kinematic outcomes. EMG will be analysed to differentiate phasic activity patterns of the muscles in question The cross correlation analysis will also be carried out to see if there is any evidence of overlap of EMG between the 2 muscles by comparing EMG measured with surface and fine wire electrodes.

With electrical stimulation experiments same set of electrodes will be used and the EMG will be analysed in similar fashion (cross correlation studies) to see isolation of response to stimulation.

Secondary outcome

There are no secondary outcome parameters.

Study description

Background summary

Anatomically gasrocnemius and soleus are grouped together and called triceps

surae. However they consist of 2 distinct muscles, one of which is bi-articular and the other is mono-articular. The fibre composition of the 2 is also different. Gastrocnemius has predominantly fast twitch fibres where as soleus consists predominantly of slow twitch fibres. Functionally these 2 muscles could be very different. Descriptions found in the literature concerning function of these 2 muscles state that they function similar to one another. However, due to close proximity, the surface electrodes placed on gastrocnemius during gait studies are bound to show cross talk from soleus. The function of these two muscles could only be differentiated using both, surface and fine wire electrodes simultaneously.
For some years electrical stimulation of the calf muscles has been considered as a possible solution for the lack of acceleration during gait in subjects who have had stroke. However, the attempts to improve their gait have been unsatisfactory. This may be due to the anatomical and functional differences or may be due to meer closeness. Generally, implantable electrodes are the most ideal method for stimulation of muscles in isolation however in many cases they are not as practical as surface electrodes. The first step in this direction would be to determine if we can effectively stimulate these underlying muscles selectively using surface electrodes.

Study objective

The objective of the study is primarily to study functions of gastrocnemius and soleus during gait individually. Secondly, to determine to what degree stimulation of the gastrocnemius and soleus can be achieved, in isolation or in combination, using surface stimulating electrodes.

Study design

Fundamental theory forming observational study.
The use of 3-D measurement system such as VICON and simultaneous use of surface and fine-wire EMG will help define the exact functions of the two muscles in kinematic and kinetic terms. The use of surface and fine wire electrodes will also enable us to explore the extent of cross talk during natural action of the muscles in question and that during neuromuscular electrical stimulation
After placement EMG electrodes selectivity of the insertion site will be tested by asking the subject to perform muscle specific movements. Markers will be placed. The subject will be asked to walk at different walking speeds during data collection.
For the stimulation part of the study: The muscles will be stimulated using surface electrodes. Four different stimulation electrode placement configurations will be examined. Stimulation parameters: biphasic pulses with pulse duration 350µs, frequency 20 pps, 35 pps & 45 pps. EMG will be recorded from all electrodes during stimulation
After the data collection the electrodes will be removed.

Study burden and risks

Besides a little discomfort at the time of insertion of fine wire electrodes it is expected that the subjects will experience no further pain or discomfort. In general, there will be no health risks involved in participating in the project. On rare occasions the tip of the fine wire electrode breaks and is left behind in the muscle, however, due to inert properties of the metal and being sterile it causes very little problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Able bodie adults, age between 18 and 65years, without any musculoskeletal abnormalities

and normal walking function.

Exclusion criteria

Subjects with gait abnormalities or musculoskeletal abnormalities, younger than 18 or older than 65 years.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2006
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-05-2006
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12104.080.06