Measuring muscle functional characteristics with high resolution MRI and DTI

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To identify characteristics of the spastic flexor carpi ulnaris muscle (FCU), and the intra-, inter-, and extramuscular connective tissues using high resolution MRI.

Ethical review Approved WMO

Status Pending

Health condition type Muscle disorders

Study type Observational invasive

Summary

ID

NL-OMON32026

Source

ToetsingOnline

Brief title

FCU in MRI

Condition

- Muscle disorders
- Soft tissue therapeutic procedures

Synonym

cerebral palsy, spasticity

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: phelps stichting voor spastici

Intervention

Keyword: DTI, force, MRI, muscle

Outcome measures

Primary outcome

Muscle volume, muscle fascicle length, moment arm, amount and nature of the

connective tissues

Secondary outcome

none

Study description

Background summary

When performing tendon transfer surgery of spastic muscles in cerebral palsy, a surgeon is confronted with dilemmas concerning what muscle to transfer, how the muscle should be mobilized, which route it should take, and at what tension it should be inserted, considering the individual needs of the patient. There is not an evidence-based answer to, nor consensus on any of these questions. Knowledge of the biomechanics of tendon transfer and on the functioning of spastic muscle is imperative for appropriate surgical planning to meet the requirements of an optimal muscle balance, and to optimize treatment. However, estimation of muscle function is difficult because the access to human muscles is limited to the operation theatre. A non-invasive method to visualize parameters that determine muscle function would allow for evaluation of function before and after tendon transfer surgery.

Study objective

To identify characteristics of the spastic flexor carpi ulnaris muscle (FCU), and the intra-, inter-, and extramuscular connective tissues using high resolution MRI.

Study design

A prospective observational study.

A series of MRI images of the forearm is gathered twice for both the patients

and the volunteers. Each series will take about 40 minutes.

Study burden and risks

This research aims no direct therapeutic effects for the participants. This study is deemed to be group-related, because spasticity is a congenital disorder that is mostly treated at young age; most patients are between 8 and 18 years old. We will only include patients that are 12 years or older. The non-spastic volunteers are adults. The risks of MRI are small and acceptable.

Contacts

Public

Academisch Medisch Centrum

meibergdreef 9
1100 DD Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

meibergdreef 9 1100 DD Amsterdam Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Patients with cerebral palsy selected for flexor carpi ulnaris to extensor carpi radialis brevis transfer

A minimum age of 12 years old; Controls:

- Healthy volunteers that have no history of trauma or any other problem to their non-dominant arm
- A minimum age of 18 years old

Exclusion criteria

Not able to understand the written informed consent Not able to extend the elbow further than 20 degrees of flexion Unable to lie flat on stomach Claustrophobia, or unable to lie still for 20 minutes

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled
Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-06-2008

Enrollment: 40

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

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 NL22795.018.08