

Electrocortical activity during force control movements in patients with anterior cruciate ligament (ACL) reconstructions versus patients with ACL deficiency versus healthy controls.

Published: 19-01-2017

Last updated: 15-05-2024

Examining the hypothesis that patients with ACL deficiency and patients with ACL reconstructions, despite comparable force-reproduction capacities with the affected, dominant right leg, have a significant altered EEG Theta-activity in the motor...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43257

Source

ToetsingOnline

Brief title

Electrocortical Activity in Patients with ACL ruptures

Condition

- Tendon, ligament and cartilage disorders

Synonym

Neural plasticity/Changes in brain activation pattern

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente

Source(s) of monetary or material Support: financiering dmv eigen middelen OCON

Intervention

Keyword: Anterior cruciate ligament deficiency, Anterior cruciate ligament reconstruction, Electrocortical activity, Neural plasticity

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in EEG Theta activity during the force-reproduction task between the ACL deficient group, the ACL reconstructed group and the healthy controls. The Theta-power consists of all waves in the frequency spectrum between 4.75 Hz en 6.75 Hz in the repetition period (where no visual feedback is present) in both measurement blocks (B1 and B2). Thereafter, a logarithmic transformation of the power values is done to stabilize the power values for the statistical analysis. The stabilized Theta-value (of blocks B1 and B2) are then compared between the ACL deficient patients, ACL reconstructed patients and the healthy controls.

Secondary outcome

The differences of (a), (b) and (c) between the ACL deficient group, the ACL reconstructed group and the healthy controls. The differences are examined using the mean values and standard deviations of all groups:

a. The alpha-2-EEG power (Hz): The alpha-2-power is examined in the same way as the Theta-power (see primary outcome). With the difference, the alpha-2-power consists of the frequencies between 9.75Hz and 12.5Hz. The powers of the

alpha-1 (7-9.5Hz), beta-1 (12.75-18.5) can also be obtained in the same way.

b. EMG activity: EMG activity is determined with help of electrodes at the m.

rectus femoris (RF), m. vastus medialis (VM) and m. vastus lateralis (VL) in

the last millisecond before the maximal angle is reached, because the

quadriceps forces are maximal at this moment.

c. Mean force-reproduction and standard deviations: the mean is calculated by

the maximal force value of every repetition divided by the number of

repetitions in the period without visual feedback (20 repetitions)

Besides, the differences of the primary outcome and the outcomes mentioned

above (a), (b) and (c) are determined between the force-reproduction periode

without visual feedback (B1 and B2) and the force-reproduction with additional

feedback (B3 and B4) for the ACL deficient, the ACL reconstructed and the

healthy control group In all cases the differences are compared between groups

using the mean values and the standard deviations

Study description

Background summary

Nowadays, the (operative and conservative) treatment and the rehabilitation after an anterior cruciate ligament (ACL) injury focuses on the restoring of mechanical stability. However, despite the restored mechanical stability a lot of patients have re-ruptures or remaining symptoms of instability. A possible explanation for this large number of re-ruptures is the lack of, or change of, sensory input from the affected knee. As a result, the central nervous system receives adjusted information and adapts to the new situation, a process called neural plasticity.

The biomechanical function of ACL patients is extensively investigated, yet neural plasticity is hardly studied. Biomechanical research shows that postural

control and landing tasks are executed comparable by ACL patients and healthy controls with eyes open. However, when eyes are closed the execution is significantly diminished in ACL patients. This implies the additional need of visual feedback in ACL patients. Earlier research, which examines the brain activity in ACL reconstructed and ACL deficient patients, has shown an increased activation of the visual cortex during simple movements with the affected leg compared to legs of healthy controls.

Study objective

Examining the hypothesis that patients with ACL deficiency and patients with ACL reconstructions, despite comparable force-reproduction capacities with the affected, dominant right leg, have a significant altered EEG Theta-activity in the motor cortex during a repetitive force-reproduction task compared to the dominant right leg of the healthy controls.

Study design

A cross-sectional, three-armed case-control study, consisting of twelve healthy controls, twelve ACL deficient patients and twelve ACL reconstructed patients.

Study burden and risks

Participation to this research takes sixty minutes of the subject's time, in addition to the regular care. This is considered to be a small load to the patient, especially because the appointment can be coupled to an existing appointment (if applicable) and otherwise can be planned at a time of choice of the patient (potentially in the evenings). Participation in this research has no consequences for the regular care of the patient.

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

General inclusion criteria:

- Tegnorscore > 4
- Age between 18 and 30 years at the moment of inclusion
- The right leg is the dominant leg;Additional inclusion criteria ACL reconstruction group:
 - primary ACL reconstruction
 - Date of measurement and date of reconstruction are not less than nine months but not more than fifteen months from each other.
 - Date of rupture and date of reconstruction surgery are not more than five months from each other.;
- Additional inclusion criteria ACL deficient group:
 - Date of measurement and date of rupture are not less than seven months but not more than seventeen months from each other. ;
- Additional inclusion criteria control group:
 - No knee damage (bilateral) in history
 - No physical limitations at the moment of measurement

Exclusion criteria

- Complications during rehabilitation (re-ruptures, additional knee damage and/or no (expected) functional recovery after 12 months
- Epilepsy and/or other brain diseases
- Pregnancy;Additional for the ACL reconstructed and ACL deficient groups:
 - Additional ligament injury at the moment of ACL rupture
 - ACL deficiency or ACL reconstruction at the contralateral knee

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2017
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO	
Date:	19-01-2017
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

ID: 27640

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL59713.044.16
Other	nog niet bekend (volgt binnen 4 weken)
OMON	NL-OMON27640

Study results

Date completed: 07-06-2018

Actual enrolment: 27

Summary results

Trial is ongoing in other countries