Electrocortical activity in ACL patients

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27640

Source NTR

Health condition

ACL deficiency ACL reconstruction Neural plasticity

VKB deficiency VKB reconstructie Neurale plasticiteit

Sponsors and support

Primary sponsor: OCON Hengelo (Orthopedic Department of Ziekenhuisgroep Twente) **Source(s) of monetary or material Support:** Own financial recourses of OCON Hengelo

Intervention

Outcome measures

Primary outcome

- EEG Theta activity

Secondary outcome

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- EEG Beta-1, Alpha-1, Alpha-2 activity
- EMG activity
- Force reproduction capacity

Study description

Background summary

Rationale: 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.

Objective:

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

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

Study population: All subjects are sportively active persons (Tegner score \geq 5) aged between 18 and 30 years old. Additionally, the subjects in the ACL reconstruction group have to be one year +/- three months after reconstruction surgery. The subjects in the ACL deficient group have to be one year +/- five months after their rupture. Most important exclusion criteria are the presence of additional ligament damage and/or brain disorders. Main study parameters/endpoints:

Primary endpoint: 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. Thereafter, a logarithmic transformation of the power values is done to stabilize the power values for the statistical analysis. The stabilized Theta-value in both measurement blocks is then compared between the ACL deficient patients, ACL reconstructed patients and the healthy controls.

Study objective

Patients with an ACL deficiency and patients with an ACL reconstruction have a significant changed EEG Theta-activity during a force-reproduction task compared to healthy controls, despite comparable force-reproduction capacities.

Study design

One timepoint one-year after ACL rupture (ACL deficient group) or ACL surgery (ACL reconstruction group).

Intervention

not applicable

Contacts

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Eligibility criteria

Inclusion criteria

General inclusion criteria:

- right footed

- Tegnerscore more than 4
- aged between 18 and 30

Subjects included in the ACL reconstructed group had to meet the following additional criteria:

- Primary rupture of ACL of the right knee

- Date of reconstruction surgery and date of measurement are not less than nine months and not more than fifteen months from each other

- Data of ACL rupture and date of reconstruction surgery are maximal five months from each other

Subjects in the ACL deficient group had to meet the following additional criteria:

- Primary rupture of the ACL of the right knee

- Data of ACL rupture and date of measurement are not less than seven months but not more than seventeen months from each other.

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Subjects included as healthy controls had to meet the following additional criteria:

- No history of knee damage (at both sides)
- No motor disabilities at the moment of measurement

Exclusion criteria

- Complications during rehabilitation (re-ruptures, additional knee damage and/or no (expected) functional recovery after welve months

- Epilepsy and/or other brain disorders

- Precense of muscular, neurologic or vascular defects which may influence the healing and/or rehabilitation

- Heavy physical or muscular mental excercise less than 24 hours before the measurement.
- Pregnancy

Subjects in the ACL reconstructed and ACI deficient group are thereby excluded when the following additional exclusion criteria are met:

- Additional knee ligament injury at the moment of ACL rupture
- ACL reconstruction or deficiency at the contralateral side.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	08-02-2017
Enrollment:	33
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	02-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43257 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6066
NTR-old	NTR6213
ССМО	NL59713.044.16
OMON	NL-OMON43257

Study results

Summary results

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Not publicated yet