Electrocortical activity in ACL patients

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27640

Bron
NTR

Aandoening

ACL deficiency
ACL reconstruction
Neural plasticity

VKB deficiency
VKB reconstructie
Neurale plasticiteit

Ondersteuning

Primaire sponsor: OCON Hengelo (Orthopedic Department of Ziekenhuisgroep Twente)
Overige ondersteuning: Own financial recourses of OCON Hengelo

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- EEG Theta activity

Toelichting onderzoek

Achtergrond van het onderzoek

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 ≥ 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 ACl 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving nog niet gestart

(Verwachte) startdatum:	08-02-2017
Aantal proefpersonen:	33
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-02-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43257
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
Not publicated yet