Functional performance after Ligamys Surgery, a case -matched study

Gepubliceerd: 20-09-2018 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON22347

Bron
NTR

Aandoening

Ligamys, voorstekruisband, DIS, Dynamic intraligamentary stabilization, ACL, Anterior cruciate ligament.

Ondersteuning

Primaire sponsor: MC Slotervaart
Overige ondersteuning: MC Slotervaart

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Limb Symmetry Index (LSI), measured by single leg hoptest.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In the Netherlands, between 8000-9000 ACL reconstructions are performed annually. Contemporary use is made of two surgical techniques, namely the Hamstring graft (HS) and bone-patellar tendon-bone graft (BPTB). This transplant has been the gold standard in recent years when it comes to reconstruct the anterior cruciate ligament. New insights into the knee surgery show that it is possible to repair the anterior cruciate ligament. Recent studies have shown that a self-healing process is possible in the anterior cruciate ligament. In addition to the BPTB and hamstring tendon graft, nowadays a new technique is used, namely dynamic intraligamentary stabilization or Ligamys. The Ligamys methode preserves the native ACL tissue, which contains the sensory nerve fibers, theoretically this will leed to a better proprioception.

Objective:

The primary purpose of this study is to assess non-inferiority in functional performance of the knee after Ligamys surgery compared to healthy controls at one to two years after surgery.

Study design:

This research concerns a cross-sectional non-inferiority case-matched study in subjects who have been operated using the Ligamys method, compared with a healthy case-matched control group.

Study population:

The population consists of patients who have undergone a Ligamys surgery at least one year post surgery and case matched healthy controls. The aim is to include 48 patients in both groups.

Main study parameters/endpoints:

The main endpoint in this study is the Limb Symmetry Index (LSI) of the single hoptest for distance to identify functional assymetry. Seconday, the study will use single leg triple hop test, the side hop test, and The Joint Position Sense Test to assess proprioception. Additionally patients will fill out the IKDC and Tegner Activity Scale.

Doel van het onderzoek

The primary goal of this study is to describe the functional performance tests of successfully treated Ligamys patients and compare this to healthy controls. The expectation with this research is that the Ligamys method meets the 90% LSI on the hop tests one to two year after surgery.

Onderzoeksopzet

single observation: all measurements will be performed between sept 2018 and sept 2019

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Male/ female sporters aged 21-45

- Ligamys operation 12-36 months postoperative

- Sufficient antero-posterior stability as measured on the KT1000 for both cases and controls (difference left-right <3mm, absolute value <5mm)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- History of fracture in lower extremity

- Recent hip/ knee/ ankle pathologies less than 2 year ago

- Intra articulair damage lower extremity

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-09-2018
Aantal proefpersonen:	96
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48879
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7271
NTR-old	NTR7486
CCMO	NL64718.048.18
OMON	NL-OMON48879

Resultaten

Samenvatting resultaten
N/A