Lidocaine injections in the m. Vastus intermedius and m. Rectus femoris

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20633

Source
NTR

Brief title
TBA

Health condition

Stroke

Sponsors and support

Primary sponsor: Roessingh Research and Development (Enschede)
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Knee flexion during gait

Secondary outcome

Kinetics and kinematics of the ankle, knee, hip and pelvis and BORG and VAS questionnaires

on knee stability.

Study description

Background summary

The current treatment of stiff knee gait, that focusses at the main causes namely over activity of the m. rectus femoris, is not effective in all patients with a CVA (Cerebro Vascular Accident). Literature also describes over activity of the m. vastii as a cause of stiff knee gait. Chemodenervation can be used to reduce muscle over activity. The efficiency of treatment in patients with stiff knee gait could be increased by chemodernervation of the m. vastus intermedius and the m. rectus femoris. The study is searching for the effect of lidocaine injections in both muscles on the gait pattern.

Objective of the study: Determining the effect of chemodenervation by lidocaine of the m. vastus intermedius and the m. rectus femoris in stroke patients presenting a stiff knee gait.

Study design: Before-after design with no control group.

Study population: 18 subjects with a CVA presenting with stiff knee gait.

Intervention: lidocaïne injections in the m. vastus intermedius and the m. rectus femoris.

Primary study outcome: Knee flexion during gait

Secundary study outcomes: Kinetics and kinematics of the ankle, knee, hip and pelvis (VICON, EMG) and questionnaires (BORG,VAS) on knee stability.

Study objective

Chemodenervation by lidocaine of the m. vastus intermedius and the m. rectus femoris improves gait pattern in stroke patients presenting a stiff knee gait.

Study design

None

Intervention

Chemodenervation by lidocaine of the m. vastus intermedius and the m. rectus femoris

Contacts

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Eligibility criteria

Inclusion criteria

Age > 18 - Stroke occurred over 6 months ago - patient presents stiff knee gait - patient able to walk independently (Functional Ambulation Categories score (FAC) ≥3) - over activity of the m. vastus intermedius and m. rectus femoris - Patient is orientated in time, place and person and is able to understand and follow instructions

Exclusion criteria

Existing pathologies or problems that are not caused by a CVA, that are of influence on the gait pattern - Allergy to lidocaine or other elements found in lidocaine hydrochloride - inflammation in the injection area

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-09-2019
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
NTR-new	NL8018
Other	MEC TWENTE : P19-04

Study results