The Trigger of the First Trial Effect: examing pure Sensory Polyneuropathy Patients

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To determine the influence of a pure sensory polyneuropathy on balance correction in light of the first trial response and in light of multiple succesive identical perturbations, compared to healthy control subjects.

Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON36041

Source
ToetsingOnline

Brief title
FTE in Polyneuropathy Patients

Condition

- Diabetic complications
- Peripheral neuropathies

Synonym
Sensory Polyneuropathy; sensory loss in the feet and lower legs

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Balance control, First Trial, propriocepsis, Trigger

Outcome measures

Primary outcome

1. Balance of sensory polyneuropathy in patients compared with that of healthy control subjects (expressed in Center of Mass movement that occurs after the platform tilts).

Secondary outcome

- Body movements based on 18 different points of limbs, trunk and pelvic tilts of the platform with polyneuropathy in patients compared to healthy controls.

- Muscle activity of ten muscles during tilts of the platform measured using surface electromyography.

Study description

Background summary

The balance of people can be reliably examined by posturography: a sophisticated way to analyse the balance of subjects on a fast moving tilting platform. The first response to a perturbation in healthy people shows that it is substantially different from the response to all subsequent perturbations, but only when each successive perturbation is identical. The response to the first perturbation (also called the First Trial Response) is accompanied by an excessively high degree of instability (which can be established by measuring the Center of Mass). This instability decreases rapidly when the subject comes into contact with a series of identical balance disturbances, but surprisingly immediately reappears as soon as the nature of the perturbation is adjusted. It is unclear which sensory mechanism in the body detects whether there is a new perturbation. Better understanding of this is desirable. First, it is to understand the normal physiology of human balance better, second, it is to reduce the incidence of falls in patients with balance disorders and ultimately to achief a better treatment. Our hypothesis is that proprioceptive information from the feet and lower legs are the crucial source of information that informs

the CNS about the presence of a new kind of perturbation. This hypothesis can be investigated by analysing specifically patients with a selective loss of proprioceptive information from the feet and lower legs. This occurs for example in patients with diabetes mellitus and selective sensory and length dependent polyneuropathy.

Study objective

To determine the influence of a pure sensory polyneuropathy on balance correction in light of the first trial response and in light of multiple succesive identical perturbations, compared to healthy control subjects.

Study design

observational study

Study burden and risks

Subjects will be asked to come to the neurology clinic at UMC St. Radboud to receive a physical examination. They will also be asked to complete a questionnaire regarding medical history and the balance in the daily life of the subject. Also, the balance will be briefly tested under different conditions. For the study subjects will make a trip to the university hospital in Basel, Switzerland. The experiment will be conducted the day after arrival and on that day, the subjects also travel back to the Netherlands. Travel and accommodation costs are fully reimbursed. The research itself is completely safe, since in previous studies in more than 100 patients (usually with severe balance disorders) no incidents have accured. During the study electrodes will be attached to ten places. Beforehand the skin will be shaved if necessary and disinfected at the sites. This could possibly cause a slight temporary irritation.

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

Symmetric, sensoric, distal polyneuropathy Diabets Mellitus typ I patients defined as: absence of achillestendon reflex, distal ' sock' gnostic sensoric loss.

Exclusion criteria

- neurological diseases other than proprioceptic loss in the feet, lower legs and hands
- orthopedic diseases
- vestibular diseases
- severe vision disturbances on 1 or 2 eyes (with glasses): vision below 5/60 = able to count the fingers of the examiner at 5 meters distance
- other diseases with a potentiel abnormal or disadvantageous effect on the equilibrium
- sedic medication
- bloodpressure lowering medication
- pregnancy
- age under 18 years
- Body Mass Index above 25kg/m2

Study design

Design

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:	Pending
Start date (anticipated):	15-04-2011
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-06-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL35721.091.11