Using the Vestibular Labyrinthine Substitution system in daily life

Published: 27-02-2012
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To objectify the effect of the VLS-system during daily use regarding postural stability and quality of life.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37351

Source
ToetsingOnline

Brief title
Using the Vestibular Labyrinthine Substitution system in daily life

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
balance disorder, bilateral vestibular loss

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bilateral, labyrinthine, substitution, vestibular

Outcome measures

Primary outcome

The effect of the VLS-system during daily use regarding postural stability and

quality of life, through assessment of:

• Stabilometry (sway area and sway path)

• Quality of life questionnaires

Secondary outcome

not applicable

Study description

Background summary

Bilateral vestibular loss represents a major handicap with strong balance disturbances, higher risk of fall, visual symptoms (oscillopsia) and a loss of autonomy. There is still no therapy is available. At current, development of a vestibular implant (VI) is our main goal. In order to achieve this goal, a so called Vestibular Labyrinthine Substitution system (VLS) is developed. The VLS, a fully ambulant system, contains a 3D sensor for linear accelerations, a processor and a belt with actuators. It functions best with people who have major balance problems. Studies show that in the majority of patients using the VLS-system, significant improvements in balance during gait are obtained, as well increased confidence, independence and a feeling of balance. Until now, all tests were performed in a balance lab, but never during daily life. This study investigates whether patient performance and quality of life indeed increase by using biofeedback in a daily situation, for a longer period (12 weeks).

1. Janssen M, Pas R, Aarts Jet al. Clinical observational gait analysis to evaluate improvement of balance during gait with vibrotactile biofeedback. Physiother Res Int 2011.
2. Kentala E, Vivas J, Wall C, 3rd. Reduction of postural sway by use of a vibrotactile balance prosthesis prototype in subjects with vestibular deficits. Ann Otol Rhinol Laryngol 2003;112:404-9.
3. Nashner LM, Shupert CL, Horak FB, Black FO. Organization of posture controls: an analysis of sensory and mechanical constraints. Progress in Brain Research 1989; 80: 411-418; discussion 395-397.

4. Horlings CG, Kung UM, Bloem BR, Honegger F, Van Alfen N, Van Engelen BG, Allum JH. Identifying deficits in Balance control following vestibular or proprioceptive loss using posturographic analysis of stance tasks. Clinical Neurophysiology 2008; 119: 2338-2346.

Study objective

To objectify the effect of the VLS-system during daily use regarding postural stability and quality of life.

Study design

Single blinded, placebo-controlled intervention study

Study burden and risks

1. After returning written informed consent, selected patients will undergo an extensive vestibular examination (about 4 hours) which is routinely done in our ENT-Department to investigate patients with balance disorders.
2. Patients will undergo also a one-day-testing phase, as explained in the protocol.
3. Patients are scheduled for extra visits to the outpatient department, including questionnaires and vestibular examination.
4. Patients have to wear a non-invasive device (VLS-system) during the day for twelve weeks.
No risks are associated with the use of the VLS-system.

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

> 18 years old
Bilateral loss of vestibular function
Severe complaints (Quality of Life score <0.4)
Subjective feeling of increased balance during one-day-testing-phase
Giving informed consent
Caloric responses <3dgr/sec
Rotational VOR-gain 90dgr/sec by 0.1Hz of <3dgr/sec
Deviant sway path and sway area during stabilometry (conform ESCEBD)
Stand up and go test: >10sec

Exclusion criteria

Incapacitated patients (orthopaedic or ocular disorders)
Neurological disorders (central vestibular disorders)
Patients with head trauma

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-07-2012
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Vestibular Labyrinthine Substitution System
Registration:	No

Ethics review

Approved WMO

Date:	27-02-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL37934.068.12