The functional evaluation of a wearable gyroscopic actuator (GyBAR) to support balance in people with degenerative ataxia

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To evaluate the effect of the balance assisting device *GyBAR* on balance capacity during standing and gait tasks in people with pure degenerative ataxia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON51752

Source
ToetsingOnline

Brief title
GyBAR Ataxia

Condition

- Movement disorders (incl parkinsonism)

Synonym
coordination disorder, movement disorder

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ataxia, Balance, Medical device

Outcome measures

Primary outcome

Participants will perform 6 tasks. We have defined a main study parameter per task

Task 1: Quiet stance for 30 seconds

Main study parameter: the root mean square of center of pressure velocity

Task 2: Walking at self-selected comfortable speed for 3 minutes on the treadmill

Main study parameter: root mean square of mediolateral center of mass position

Task 3: 360° turn-in-place

Main study parameter: jerkiness of the performed turn

Task 4: Quiet standing in tandem stance (heel touches toe) for as long as possible

Main study parameter: maximum duration (seconds) of standing in tandem stance.

Task 5: Walking in tandem gait for as many steps as possible

Main study parameters: maximum number of correct steps taken by the participant

Task 6: Balance recovery from treadmill-induced sideways balance perturbations.

Main study parameter: success of a feet-in-place recovery (i.e. the participant are able to recover their balance without taking a step).

Secondary study parameter: margin of stability, defined as the distance between the body*s extrapolated center of mass (a measure that incorporates both center

of mass position and velocity) and the edge of the base of support.

Secondary outcome

The participant*s experience with the GyBAR as a balance assisting device will

be assessed via a 5-point Likert Scale.

Study description

Background summary

People with degenerative ataxia experience disabling balance and gait impairments. These arise due to the progressive coordination difficulties of both the extremities and trunk. As a result, falls and fear of falling are common among people with degenerative ataxia. Recently, the backpack GyBAR has been developed to provide overground balance assistance. In the current study, we will conduct exploratory measurements to evaluate the potential efficacy of the GyBAR in potential end users; individuals with degenerative ataxia.

Study objective

To evaluate the effect of the balance assisting device *GyBAR* on balance capacity during standing and gait tasks in people with pure degenerative ataxia.

Study design

An explorative observational cross-sectional study.

Intervention

Wearing of the GyBAR backpacl

Study burden and risks

The risks associated with participation will be negligible. Participants will wear a safety harness during the assessment which prevents them from falling. Burden association with the assessments will be limited, as participants will have one assessment with an expected duration of two hours.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Diagnosis of pure degenerative ataxia based on molecular diagnosis or clinical assessment by a neurologist specialized in movement disorders
- Age between 18-70 years old
- Difficulties with gait where the participant cannot perform tandem walking (heels to toes) over ten steps and staggering occurs while performing a half turn (though it is possible to complete the turn without support (Score of 2 or 3 on item 1 *Gait* of the Scale for the assessment and rating of ataxia (SARA))
- Difficulties while standing that arise when the participant is asked to stand with feet together, whereas standing in natural position is possible for over 10 seconds; (Score of 3 on item 2 *Stance* of the SARA scale)
- Being able to wear a backpack of 6 kilograms for a duration of two hours

Exclusion criteria

- Other neurological or orthopaedic conditions impacting on balance and/or gait performance.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2023
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	GyBAR
Registration:	No

Ethics review

Approved WMO Date:	26-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-05-2023
Application type:	Amendment

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	NL82737.091.22