Method development of the POWERjar device: validation study in healthy volunteers.

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- To assess the POWERjar in measuring muscle fatigue, compared to simultaneous sEMG recording- To assess the POWERjar in measuring torque- To assess the POWERjar maximal grip force and compare to maximal grip strength measured with the Jamar...

Ethical review	Approved WMO	
Status	Recruitment stopped	
Health condition type	Other condition	
Study type	Observational non invasive	

Summary

ID

NL-OMON42772

Source ToetsingOnline

Brief title POWERjar validation in healthy subjects

Condition

• Other condition

Synonym biomechanics, hand function

Health condition

biomechanics

Research involving

Human

1 - Method development of the POWERjar device: validation study in healthy volunteer ... 16-05-2025

Sponsors and support

Primary sponsor: Centre for Human Drug Research **Source(s) of monetary or material Support:** Biogen,Paid by CHDR;with partial financial support from Biogen Idec

Intervention

Keyword: Jamar, Muscle fatigue, POWERjar, surface EMG

Outcome measures

Primary outcome

- torque on POWERjar
- grip strength on POWERjar
- signal amplitude on sEMG

Secondary outcome

N/A

Study description

Background summary

To assess and quantify muscle function in neuromuscular disorders for clinical trials, surface electromyography (sEMG) is currently the gold standard to measure fatigability. However, although EMG is accurate, it also requires specifically trained staff and might not reflect clinical relevance of muscle dysfunction or weakness. The POWERjar is a measurement device that allows for the recording of grip strength and opening / closing torque of a jar, which is easy to use and distribute in late phase clinical trials. More importantly, it also has clear clinical relevance, as it imitates a task that is a typical activity of daily living. This device has only recently been developed and it is not yet clear how variables yielded by PowerJar measurements (such as torque / hand grip strength) relate to gold standard surface EMG and what the precision is of these measurements in comparison to sEMG.

Study objective

- To assess the POWERjar in measuring muscle fatigue, compared to simultaneous

sEMG recording

- To assess the POWERjar in measuring torque

- To assess the POWERjar maximal grip force and compare to maximal grip strength measured with the Jamar dynamometer.

- To assess the POWERjar in measuring time of release of grip.

Study design

Method validation study, parallel group, in healthy male and female volunteers.

Study burden and risks

Performing several hand function tests using grip strength and torque, sEMG with stickers (no needles), no risks

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

3 - Method development of the POWERjar device: validation study in healthy volunteer ... 16-05-2025

Elderly (65 years and older)

Inclusion criteria

1. Healthy male or female subjects, 21 to 80 years of age, inclusive. Healthy status is defined by absence of evidence a condition that might affect upper limb function, following an abbreviated medical screening.

2. Body mass index (BMI) between 18 and 35 kg/m2, inclusive.

3. Able to participate and willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

1. Concomitant disease or condition that, in the opinion of the Investigator, might affect upper limb function.

2. Unable to understand the study requirements and lifestyle restrictions as described in the informed consent form or unable to give informed consent due to the subject's cognitive status.

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Other	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2015
Enrollment:	60
Туре:	Actual

Ethics review

Approved WMO Date: Application type: Review commission:

08-09-2015 First submission BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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 CCMO ID NL54720.056.15