Fatigue Resistance AMErsfoort: comparison of Martin Vigorimeter and Jamar Dynamometer, elaboration of reference data and appraisal of clinical correlates.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON50557

Source
ToetsingOnline

Brief title
FRAME

Condition

- Other condition

Synonym
muscle fatigue

Health condition

er wordt geen aandoening bestudeerd, het betreft gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Opleiding Musculoskeletale Therapie (SOMT) University Campus Amersfoort
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: elderly, fatigue resistance test, frailty, muscle fatigue

Outcome measures

Primary outcome

Fatigue resistance:

assessed by both the Martin Vigorimeter and the JAMAR dynamometer in a random order (see appendix 1 for detailed description). Both tests will be performed at the same day with at least 1 hour interval. In a subgroup of participants the fatigue resistance test will be performed by a modified digital manometer and Dynamometer G200 system, and with simultaneous synchronized sEMG recording of the fore-arm muscle (all connected to a MPAQ universal amplifier, Maastricht Instruments) in order to appraise muscle fatigue curves and related muscle activation. Area under the curve and other derived muscle endurance parameters are calculated as described previously.

Secondary outcome

Figures refer to reference list in the protocol.

Explanatory outcomes

Hand function & pain: Perceived pain in the hands directly following the fatigue resistance test (Numeric Rating Scale), Hand function(Australian/Canadian Hand Osteoarthritis Index) (17), presence/number of phalangeal nodules (using standard photographic registration and visual counting). In a subgroup of participants a standard ultrasonographic assessment of the hands will be performed in order to assess the degree of osteoarthritic lesions (18).

Sarcopenia assessment according to European consensus criteria (19) including physical functioning (Short Physical Performance Battery (20), Timed Up-and-Go test (21), 2 minutes step test (22), flexicurve ruler (23) and body composition (Bio-electrical Impedance, Quadscan4000, Bodystat, Ashhurst, New Zealand) (24).

Self-perceived fatigue & physical activity: MOB-Tiredness scale (25), Multidimensional Fatigue Inventory (26) and Yale Physical Activity Questionnaire (27).

General health and quality of life: co-morbidity & medication use using self-report questionnaires; Medical Outcome Study (MOS) Short-form (28); cognitive functioning (MMSE (16); dependency for activities of daily life (basic (29) & instrumental (30) ADL)

Inflammatory parameters: serum obtained from non-fasting venepuncture, stored at -80°C for ulterior determination of circulating markers of inflammation

(including IL-6, sTNFR1, IL-10, IL-1RA, IL-8, HSP70) as described previously

(31,10).

Study description

Background summary

In a series of 10 original studies (references 1-10, see protocol) we have introduced, refined and validated a new assessment method for muscle fatigue resistance as a direct and objective outcome parameter of the exhaustion component of Frailty in elderly persons. Our test is now internationally accepted and several researchers as well as clinicians are using it. The fatigue resistance test has been validated for the Martin Vigorimeter (KLS Martin Group, Tuttlingen, Germany), a device to measure grip strength consisting in a rubber bulb connected to a manometer. Since this device is very comfortable and allows performing a dynamic contraction (the rubber bulb is compressible), it is highly suitable to assess sustained maximal contractions in elderly subjects. However, many researchers and clinicians are using the Jamar dynamometer (Sammons Preston, Rolyon, Bolingbrook, IL), a device designed to measure static grip strength (see figure 1B). Grip strength measures obtained by the Martin Vigorimeter have been shown to be well correlated with those obtained with the Jamar dynamometer. Though, to date, no data regarding the fatigue resistance test measured with the Jamar dynamometer are available, thus limiting the implementation of the fatigue resistance test. Validation of the fatigue resistance test with the Jamar dynamometer would improve its implementation in daily practice.

Study objective

The primary objective of this research project is to further validate the fatigue resistance test by comparing muscle endurance outcomes obtained by the Martin Vigorimeter and the Jamar Dynamometer in subjects of different ages and clinical condition.

A second objective is to propose normative data for both systems that can be used for clinical interpretation of the muscle endurance scores.

A third objective is to appraise the importance of clinical correlates in the interpretation of muscle fatigue resistance.

Study design

Cross sectional study, explorative

Study burden and risks

The subjects will be assessed only once, during 1 h 15 min with 1 hour interval between the fatigue resistance tests. During the fatigue resistance test only the dominant hand is tested. The subject is asked to squeeze the large bulb of the Martin Vigorimeter / the handle of the JAMAR dynamometer twice. First as hard as possible and a second time as long as possible untill force has dropped below 50%. This test as well as the other evaluations do not influence subject's integrity. They are commonly used diagnostic tests in physical therapists' daily practice to evaluate muscle function and physical performance. Prior to the assessment the investigators are trained to standardize the protocol. During the assessments an observator will be present to control the procedure.

Blood sampling (20 ml. per sample) normally is innocent, but sometimes is accompanied by minor inconveniences such as pain during or after the puncture, or a bruise after sampling.

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

Young, healthy subjects aged 18-30 years: completely healthy, no medication use, no impairments interfering with muscle fatigue resistance test, normal physical activity (i.e. at least 150 minutes/week at moderate intensity but no competitive sports).
Community-dwelling subjects aged >30years: living independently in the community, no functional disability of the dominant upper extremity (paresis/paralysis, tremor or recent surgery), normal cognitive functioning (Mini-Mental State Examination [MMSE] score >23/3016).

Exclusion criteria

Pregnant women are excluded.
Acute or uncontrolled conditions, chronic inflammatory pathology and/or central nervous disease (e.g. Parkinson*s disease, Multiple Sclerosis, Cerebro-Vascular Accident).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2015
Enrollment:	800

Type:	Actual

Ethics review

Approved WMO Date:	31-03-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	02-10-2017
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	04-01-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL51425.096.14