Gait analysis of servicemen after combat foot injuries during operation Task Force Uruzgan.

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To assess functional outcome and using gait analysis to quantify kinematic and kinetic abnormalities of servicemen who suffered foot injuries due to combat actions.

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

Summary

ID

NL-OMON44158

Source
ToetsingOnline

Brief title
Gait analysis after combat foot injury.

Condition

- Fractures

Synonym
foot injury, fractures of talus and/or calcaneus and/or navicular bone

Research involving
Human

Sponsors and support

Primary sponsor: Militair Revalidatiecentrum
Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Keyword: combat, foot, gait, injury

Outcome measures

Primary outcome

- The mean (SD) step width, step length, step frequency and average self-paced speed.

- The mean (SD) range of motion of ankle (dorsal/plantar flexion and ab-/adduction).

- Peak Power ankle joint (W/kg)

Secondary outcome

- Physical Performance tests: the CHAMP, existing of

- The SLS:the amount of time an individual can stand on one lower limb. The patient performs at least 1 trial for each lower limb and up to 3 trials for each lower limb. Once 30s is achieved with one lower limb, no further trials will be performed for that limb.

- The ESST: it measures the number of lateral shifts over 4 meter completed in 10 s. The best of 3 trials will be calculated.

- The TT: The patient sprints 10 meters forwards, 5 meters to the right, 10 meters to the left, 5 meters to the right 10 meters backward (T-shape). The best of 3 trials will be calculated.

- The IAT: the participant runs forward and back 10 m, weave up and back through a middle row of 4 cones and repeat the forward and back 10 meters run to conclude the test. The length and width of the course is 10 m by 5 m. The best of 3 trials will be calculated.

The CHAMP scoring system produces *CHAMP Scores* with a range from 0 to 10 for each of the 4 items. The converted *CHAMP Scores *of the 4 CHAMP items are added together to produce a composite or Total CHAMP Score ranging from 0 to 40 with 40 representing the highest level of performance and 33 * representing the threshold level of performance equivalent to Active Duty Service Members.

- Lower Extremity Functional Scale (LEFS); The LEFS is a 20-item condition-specific questionnairede signed for individuals with musculoskeletal conditions of the lower extremity. Each item of the LEFS scores on a 5-point scale ranging from 0 to 4 points, 0 being an *extreme difficulty or unable to perform activity* and 4 being *no difficulty*.

Study description

Background summary

During combat operations, injuries to the extremities require the greatest medical resources, disable the most servicemen and have the biggest disability benefit costs. The size and scale of ankle and foot injury is profound. Foot injuries have a significant effect on quality of life in poly-trauma patients. Fifty-eight Dutch servicemen who suffered combat-related injuries during operation *Task Force Uruzgan* (TFU) received a rehabilitation program in the Military Rehabilitation Center (MRC). Mobility measured by the Lower Extremity Functional Scale (LEFS) accounts for 51% of health related quality of life (HRQoL) 2.5 years after the incident. Guidelines for foot and ankle rehabilitation are limited in this population.

Study objective

To assess functional outcome and using gait analysis to quantify kinematic and kinetic abnormalities of servicemen who suffered foot injuries due to combat actions.

Study design

Observational study.
The GRAIL (Gait Real-time Analysis Interactive Lab) system will be used to measure walking-speed, step parameters and joint angles. Physical performance tests will be performed; The Comprehensive High-Level Activity Mobility Predictor (CHAMP). The CHAMP consists of 4 tests: Single Limb Stance (SLS), the Edgren Side Step Test (ESST), the T-Test (TT) and the Illinois Agility Test (IAT). The Lower extremity functional scale (LEFS) will be filled out by the participant. The relationship between gait parameters, physical performance tests and the LEFS will be calculated.
To test whether or not there is a significant difference in the mean outcome for the group with foot injuries compared to the normal group on gait analysis parameters and performance tests, the t-tests will be used when there is a normal distribution and the Mann-Whitney when there is not a normal distribution,
The influence of determinants on the LEFS the Pearson correlation coefficient will be used. It will calculate the correlation between variables and the LEFS.

Study burden and risks

The subjects have to visit the rehabilitation centre once and will perform mild physical exertion (walking) and physical performance tests. The duration of mild physical exertion is 12 minutes in total; at fixed and self paced speed. The physical performance tests will take approximately 18 minutes. Total duration of the session will be 60 minutes. Since subjects walk on a treadmill and are suspended by a safety harness system overhead which prevents the subject from falling, the risks are negligible.
Since no kinetic and kinematic data are known for blast-related foot injuries, insight in these might benefit future surgical interventions and rehabilitation programs.

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

Dutch servicemen who sustained talus and/or calcaneus and/or navicular fractures on one or both sides in Afghanistan as a result of combat actions and were repatriated because of their injuries.
A control group of 14 healthy servicemen will be included, matched on age and sex, without a history of orthopaedic, neurological or vascular injury of back or lower extremities.

Exclusion criteria

1) Not being able to walk barefoot
2) Visual impairments that can affect gait.
3) One sided amputation of the lower extremity.
4) Injury to the central nervous system.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2016
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO Date:	09-02-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-04-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL49481.028.15