PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Applicability of a walker in healthy volunteers of different ages and levels of activity

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Walkers are removable. Therefore walkers allow early physiotherapy and regular wound control. Accordingly, the volume of prescriptions is increasing. The handling of a walker is mostly under the patient's autonomous control. The prerequisite of a walker is the autonomous and appropriate application by the patient. Aim of this study was to investigate patient handling safety of a walker in a broad patient collective.

Brief Summary in Scientific Language

Various pathologies affecting the foot and ankle require immobilization. Immobilization can be achieved by various means, including white or soft cast, splint or walker. Over the last decade, walkers have become increasingly popular. This could be due to various advantages of walkers compared to traditional casting. First, walkers are removable and therefore allow early physiotherapy and regular wound control. Second, they allow full weightbearing due to a durable plastic shell and sole. Third, most walkers are adjustable and therefore can be adapted to current soft tissue conditions. The prerequisites for all these benefits is an easy and safe patient handling of the walker as it is removed and reapplied by the patient. Especially elderly patients might face difficulties due to visual impairment, reduced muscle strength (sarcopenia) or limited ROM (range of motion). No study has jet investigated general patient safety for any walker. Therefore, the aim of this study was to investigate patient handling safety of a commonly prescripted walker (VACO®ped) in a brought sample.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013728**
- Date of Registration in DRKS: **2018/02/16**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **782-16 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- Free text: **healthy subjects**

Interventions/Observational Groups

- Arm 1: **Healthy volunteers of different ages and levels of activity are being researched at two different times (t0, t1). During the first investigation (t0) the volunteers are being taught in the handling of the walker (VACO®ped) in small groups of 4. Afterwards the volunteers are asked for applying the walker on their own, as previously learned. Wether the volunteers are doing every important step of the application procedure is controlled by the help of an 8-step protocol. Next is the measurement of strap tightness and heel lift-off. Strap tightness will be assessed as the penetration depth of a wedge at a constant force of 2 kg (20N). The wedge is inserted between the strap and the top cover of the boot and the penetration depth of the wedge is being measured in centimeters. To check the heel mobility, the volunteer is asked to lift the heel as far as possible within the walker. The distance between the heel and the bottom of the walker is assessed in centimeters. Finally the volunteers are asked to subjectivly judge, whether the walker was applied correctly (right/false) and if the application was easy or difficult. One to two weeks after the first investigation (t1) the investigation is repeated by the same volunteers without being instructed first.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**

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Study Type Non-Interventional: **Other**

- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health economics**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary Outcome is the 8 - Point Application Score. First measurement point is the day of study inclusion (t0). Second measurement point is 1 to 2 weeks after t0 (t1). The primary outcome parameter is determined by a protocol. On the basis of this protocol (consisting of 8 subitems, dichotomous scaled) it will be checked whether the volunteer is doing every important substep of the application procedure.

Secondary Outcome

Secondary Outcome are strap tightness, heel lift-off and subjective judgement of the volunteers on the proper application and handling experience. First measurement point is the day of study inclusion (t0). Second measurement point is 1 to 2 weeks after t0 (t1). Strap tightness is measured as the penetration depth of a wedge. The wedge is inserted between strap and top cover of the boot at a constant force of 20N (2kg). The penetration depth of the wedge in centimeters reflects the strap tightness. Heel lift-off is also measured in centimeters. The distance between heel and sole of the boot is measured with the help of a prefabricated tool in 0,5 increments. The subjective judgement on the correct application and handling experience is asked by means of a dichotomous scaled questionnaire (right/false or rather easy/difficult).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/02/01**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **95 Years**

Additional Inclusion Criteria

Age between 18 and 95 years; Informed consent; No musculoskeletal impairment within the last six months.

Exclusion criteria

Cognitive, neurological or obvious physical impairment.
Acute impairment of the foot and ankle within the last 6 months.
Pregnancy.
Inability to give informed consent.

Addresses

- **Primary Sponsor**

  Klinik für Allgemeine, Unfall- und Wiederherstellungschirugie, Klinikum der Universität (LMU) München
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- **Contact for Scientific Queries**

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■ **Collaborator, Other Address**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/03/31**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*