

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

Trial Description

Title

How Shoulder Immobilization Influences Daily Physical Activity - An Accelerometer Based Study

Trial Acronym

AWTS

URL of the trial

[---]*

Brief Summary in Lay Language

Regular physical activity is a clearly proven health resource in prevention and rehabilitation. Physical activity can help prevent cardiovascular disease, diabetes II and obesity as well as numerous other physical and mental disorders. After operations, the rehabilitation phase is used to prevent chronic and degenerative diseases and to speed up the healing process. The immobilization of the shoulder joint is a necessary component in the postoperative treatment following shoulder injuries or reconstructive operative interventions in case of shoulder conditions caused by degenerative diseases. Physical activity in this context is thus potentially very significant for elderly patients. The aim of this study is thus to measure daily activity in the case of an immobilized shoulder joint in order to derive a transfer to the postoperative therapy program following shoulder operations and to expand possible recommendations for rehabilitation therapy. 21 healthy volunteers were immobilized in an orthosis (DJO Ultrasling III) for 10 hours on two consecutive days. In the following week, activity was measured on the same days without the orthosis. Activity was measured by accelerometer based step count StepWatchTMActivity Monitor (SAM). A questionnaire was administered to evaluate subjective activity.

Brief Summary in Scientific Language

Purpose

The harmful effect of sedentary behavior does not receive much attention in orthopedic surgery even though immobilization, especially of the lower extremity, has been associated with reduced physical activity. Immobilization of the shoulder is common after reconstructive shoulder surgery and could also potentially lead to reduced physical activity and have a negative effect on a patient's general health.

Methods

21 healthy volunteers were immobilized in an orthosis (DJO Ultrasling III) for 10 hours on two consecutive days. In the following week, activity was measured on the same days without the orthosis. Activity was measured by accelerometer based step count StepWatchTMActivity Monitor (SAM). Average age was 26 +/-3 years. A questionnaire was administered to evaluate subjective activity.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017636**
- Date of Registration in DRKS: **2019/09/13**
- 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.: **2018-290-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

- Free text: **healthy volunteers**

Interventions/Observational Groups

- Arm 1: **21 healthy volunteers were immobilized in an orthosis. In the following week, activity was measured on the same days without the orthosis. Activity was measured by accelerometer based step count StepWatchTMActivity Monitor (SAM). Therefore Interventional Group is his own control Group.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Other**
- Blinding: [---]*
- Who is blinded: [---]*



Study Type: **Interventional**

Study Type Non-Interventional: [---]*

Allocation: **Other**

Blinding: [---]*

Who is blinded: [---]*

- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Measurement was carried out on two consecutive days for 10 hours. First measurement took place with immobilized shoulder in an orthosis. In the following week, activity was measured on the same days without the orthosis. Activity was measured by accelerometer based step count StepWatchTMActivity Monitor (SAM). A questionnaire was administered to evaluate subjective activity at both times of activity measurement.

Secondary Outcome

none

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Institut für Sportmedizin, Münster**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/06/03**
- Target Sample Size: **21**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **30 Years**

Additional Inclusion Criteria

Inclusion criteria:
Between 18 and 30 years of age signed an informed consent form.

Exclusion criteria

Exclusion criteria:
Acute or chronic diseases of the cardiovascular system or the passive / active musculoskeletal system.

Addresses

■ Primary Sponsor

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URL: **https://www.ukm.de/index.php?id=orthopaedie_uebersicht**

■ Contact for Scientific Queries

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/10/28**

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.