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Electric muscle stimulation for treatment of functional shoulder instability

Submission date
25/03/2019

Recruitment status
No longer recruiting

Registration date
05/04/2019

Overall study status
Completed

Last Edited
03/05/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Functional posterior shoulder instability (FPSI) is a force imbalance of stabilizing shoulder muscles which mainly affects teenagers and young adults with severe effects on shoulder function. Patients with FPSI suffer from repetitive posterior displacements every time the shoulder passes a particular phase of movement in the mid-range of motion. Severely restricted shoulder function and symptoms such as pain, loss of range of motion due to weakness or blockage that inhibits any further movement, as well as a strong feeling of instability, are reported by the affected patients. Current therapy includes conservative as well as surgical stabilization attempts. In daily clinical practice, however, standard physiotherapy is often ineffective and after years of unsuccessful conservative treatment, patients affected with FPSI finally undergo a surgical stabilization attempt with results that are often worse than before. In a study with 5 participating centres, a promising therapy concept based on electric muscle stimulation shall be compared to the current standard care physiotherapy. If the results of the new treatment approach show better results than the existing standard physiotherapy, a much-needed step forward in the treatment of patients with FPSI will be achieved and likely lead to a complete change in the existing therapy for this challenging pathology. For the patients themselves, this new treatment concept possibly could represent a true „game-changer“ that might free them of the burden of FPSI.

Who can participate?
Participants over the age of 14 with FPSI will be included in this study irrespective of gender or duration of symptoms. Exclusion criteria focus on structural pathologies (static posterior migration, connective tissue diseases, degenerative joint diseases, structural defects) and other pathologies (multidirectional instability, neurological disorder or nerve injuries, existing pain syndrome, medical contraindication to EMS treatment) hindering, impeding, or prohibiting to complete the control or experimental treatment. Additionally, participants with previous participation in a pathology-targeted standardized EMS or physiotherapy protocol are excluded in order to avoid potential unwillingness to participate in or preformed mindset towards an intervention that they previously tried already without success.

What does the study involve?
The study will compare two treatment groups. The experimental intervention consists of an EMS-

based training protocol to stimulate specific muscle groups of the shoulder. The training involves a combination of certain exercises with increasing difficulty and intensity. The control intervention includes a pathology-targeted standardized physiotherapy protocol which has been developed and agreed on by international renowned shoulder experts. Both experimental and control treatment will include 18 one-hour trainings evenly distributed over a time period of 6 weeks and will be performed by the same physiotherapist at each participating centre based on standardized protocols. In the case of subjectively unsatisfying results, an optional switch (cross-over) into the other treatment group is allowed to make both potentially superior therapies available to all participants within a reasonable time (3 months after the beginning/6 weeks after the end of the intervention).

What are the possible benefits and risks of participating?
Each participant benefits by receiving an intensive, targeted and potentially equal physiotherapeutic treatment concept. The training concepts aim to increase endurance and coordination including functional training as well as strengthen specific stabilizing shoulder muscles. In addition, as part of clinical routine, each participant will receive a clinical evaluation and individualized consultation on the likelihood of reoccurring shoulder displacements. No adverse events or complications of the experimental EMS-based therapy have been observed in a pilot study.

Where is the study run from?
This study will be available in centres across Germany and Switzerland and supervised by the Charité- Universitaetsmedizin Berlin as lead centre. Further centres include the ATOS Clinic, Munich, Germany; the Annastift Hospital, Hannover, Germany; the St. Vincentius Kliniken, Karlsruhe, Germany; Schoen Clinic Düsseldorf and University Clinic Düsseldorf, Germany; and the Schulthess Clinic, Zurich, Switzerland.

When is the study starting and how long is it expected to run for?
June 2019 to June 2022

Who is funding the study?
This project is currently initiated and funded by the investigators

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Electric muscle stimulation for treatment of non-controllable positional functional posterior shoulder instability

Acronym
EMS for FPSI

Study objectives
Electrical muscle stimulation (EMS) based therapy has the same clinical effect as conventional state-of-the art physiotherapy treatment for FPSI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/08/2018, Ethics Committee of Charité – Universitaetsmedizin Berlin (Charitéplatz 1, Virchowweg 10, 10117 Berlin; +49 (0)30 450 517 222; ethikkommission@charite.de), ref: EA2 /077/18

Study design
Multi-centric randomized controlled therapeutic trial active control no masking optional cross-over design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-controllable positional functional posterior shoulder instability (FPSI).

Interventions

In a multicentric prospective randomized controlled trial, we would like to objectively assess a promising new EMS-based treatment concept which was evaluated at our institution in a prospective pilot trial involving 24 cases with previously unsuccessful conventional physiotherapy treatment of FPSI. Pathology-targeted physiotherapy is the current standard treatment of FPSI and will serve as the control intervention in the proposed trial. All involved centers as well as independent experts have specified and agreed on a standardized exercise protocol for the control intervention during a Delphi survey. The control intervention will have the same duration, intervals, and instructing physiotherapist (at each center) as the experimental intervention. An optional bi-directional cross-over into the other intervention group (experimental or control) is possible after follow-up examination at the time-point T2 (3 months after the beginning/6 weeks after the end of the intervention) in the case of subjectively unsatisfying results despite completion of the originally assigned intervention to offer both possibly superior interventions to all participants.

Experimental intervention: electrical muscle stimulation based therapy protocol
Control intervention: conventional state-of-the art physiotherapy protocol
Follow-up per patient: 0 weeks (T0), 6 weeks (T1), 3 months (T2), 6 months (T3), 12 months (T4)
Duration of intervention per patient: 6 weeks

The strict inclusion and exclusion criteria create a homogeneous group of study participants. After a patient has decided to enter the study and provided written informed consent, he/she will be randomized in one of the two treatment groups (allocation ratio 1:1). A randomization sequence will be generated electronically using Stata (StataCorp LP, Texas USA) separately for each participating center and loaded within an online study database in REDCap17 (Research Electronic Data Capture) for automatic concealed allocation. Block-randomization with blocks of 2 and 4 will be used to minimize the risk of unequal group sizes. The randomization process allows to divide the study participants into two cohorts of comparable characteristics. We will compare these cohorts with regards to potential confounding factors before the outcome analyses and adjust statistically for any observed imbalance as appropriate.

Since the main outcome measurement is a subjective score, blinding of the examiner is not necessary. Blinding of the patients themselves is not possible due to the nature of experimental and control intervention. This circumstance can potentially introduce a confirmation bias from the patients' side. However, according to the trial design, all patients with previous participation in a pathology-targeted standardized EMS or physiotherapy protocol are excluded which reduces the risk for a pre-conditioned mindset in patients.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Western Ontario Shoulder Instability Index (WOSI) at T2

Key secondary outcome(s))

1. WOSI at T1, T3, and T4.
At 0 weeks (T0), 6 weeks (T1), 3 months (T2), 6 months (T3), 12 months (T4):
2. Subjective shoulder value
3. Impairment of daily activities
4. Sports impairment
5. Pain level

6. Range of motion
7. Strength
8. Satisfaction with treatment

Assessment of safety: Based on the complication-free pilot trial, no adverse events are pre-specified but continuous recording of unexpected adverse events will be executed in both treatment arms.

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Non-controllable positional functional posterior shoulder instability (FPSI)
2. Aged 13 years or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
13 years

Sex
All

Total final enrolment
59

Key exclusion criteria
1. Multidirectional instability
2. Static posterior instability/migration
3. Connective tissue disease
4. Degenerative joint disease
5. Structural defects visible on pre-treatment MRI
6. Neurological disorder or nerve injury
7. Existing pain syndrome (defined by pain at rest or during motion, which is not caused by dislocation but impedes physiotherapeutic training and/or EMS)
8. Non-tolerance of EMS treatment (e.g. cardiac pacemaker)
9. Previous participation in a pathology-specific standardized EMS or physiotherapy protocol

Added 21/02/2020:
5. Structural defects visible on pre-treatment MRI:
5.1. Any acquired glenoid bone defect

5.2. Glenoid dysplasia with more than 10° of retroversion (of cartilagineous surface) according to Imhoff et al.
5.3. Convex cartilagineous glenoid articular surface
5.4. Static posterior glenohumeral decentering >55% according to Walch et al.
5.5. Degenerative changes (any visible cartilage damage or OA)

Date of first enrolment
01/06/2019

Date of final enrolment
01/01/2022

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
Charité University Hospital
Centrum für Muskuloskeletale Chirurgie
Augustenburger Platz 1
Berlin
Germany
13353

Study participating centre
Annastift Hospital
Anna-von-Borries-Straße 1-7
Hanover
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30625

Study participating centre
ATOS Clinic
Effnerstraße 38
Munich
Germany
81925

Study participating centre

St. Vincentius Clinic
Südendstr. 32
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76135

Study participating centre
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Study participating centre
Schoen Clinic Düsseldorf
Am Heerdter Krankenhaus 2
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40549

Study participating centre
University Clinic Düsseldorf
Moorenstraße 5
Düsseldorf
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40225

Sponsor information

Organisation
Charité - Universitaetsmedizin Berlin

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2024	03/05/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1.0	30/11/2019	02/12/2019	No	No
Protocol file	version v2.0	18/02/2020	18/02/2020	No	No
Protocol file	version v3.0	25/03/2020	25/03/2020	No	No
Protocol file	version v4.0	08/04/2020	04/06/2020	No	No