

Electric muscle stimulation for treatment of functional shoulder instability

Submission date 25/03/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/05/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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- Universitätsmedizin 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?

PD Dr. med. univ. Philipp Moroder
philipp.moroder@charite.de

Contact information

Type(s)

Scientific

Contact name

Dr Philipp Moroder

Contact details

Department of Shoulder and Elbow Surgery
Center for Musculoskeletal Surgery- Campus Virchow
Charité Universitätsmedizin
Augustenburgerplatz 1
Berlin

Germany
13353
+4930450652175
philipp.moroder@charite.de

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 – Universitätsmedizin 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

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

Western Ontario Shoulder Instability Index (WOSI) at T2

Secondary outcome measures

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.

Overall study start date

01/11/2018

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

Age group

Mixed

Lower age limit

13 Years

Sex

Both

Target number of participants

To be assessed for eligibility: n = approximately 87 (expected exclusion rate of approximately 25%); To be assigned to the trial: n = 65 (accounting for an expected drop-out rate of approximately 20%); To be analysed: n = 52 (calculated sample size for a power of 80%, alpha error probability of 5%, and an estimated effect size of 0.8 at 12 months)

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 cartilaginous surface) according to Imhoff et al.
- 5.3. Convex cartilaginous 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
Germany
30625

Study participating centre
ATOS Clinic
Effnerstraße 38
Munich
Germany
81925

Study participating centre
St. Vincentius Clinic
Südendstr. 32
Karlsruhe
Germany
76135

Study participating centre
Schulthess Clinic
Lengghalde 2
Zurich
Switzerland
8008

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

Study participating centre
University Clinic Düsseldorf
Moorenstraße 5
Düsseldorf
Germany
40225

Sponsor information

Organisation

Charité - Universitätsmedizin Berlin

Sponsor details

Department of Shoulder and Elbow Surgery

Center for Musculoskeletal Surgery

Campus Virchow Klinikum

Augustenburger Platz 1

Berlin

Germany

13353

+49 30 450 - 50

victor.danzinger@charite.de

Sponsor type

University/education

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Research organisation

Funder Name

Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

The results of the study are presented in a manuscript in accordance with the CONSORT guidelines and published in a scientific journal. To ensure general availability, the publication is made freely accessible. Moreover, the results will be presented at national and international conferences.

Intention to publish date

01/10/2022

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?
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
Results article		01/01/2024	03/05/2024	Yes	No