DRKS00040045

Request an update

Efficacy and safety of cardiac rehabilitation with the additional use of electrical muscle stimulation in patients with reduced and mildly reduced ejection fraction

Organizational data

DRKS ID of the study:
DRKS00040045

Recruitment status:
Recruitment is underway

Registration date in DRKS:
April 24, 2026

Last update in DRKS:
April 24, 2026

Type of registration:
Retrospective

Study acronym/study abbreviation

EMS-PL HF STUDY

website of the study

No entry

Brief description in layman's terms

Heart failure is a widespread condition in the European population. This study aims to determine whether the additional use of electrical muscle stimulation via a suit can positively influence the outcomes of standard cardiac rehabilitation in patients with reduced and mildly reduced ejection fraction. A suit will be used that enables programmable stimulation across a broad range of major muscle groups and is controlled wirelessly without external wiring.

Scientific summary

Cardiac rehabilitation is an essential component of heart failure treatment in Poland and Europe. Approximately one million people in Poland currently live with heart failure. In 2021, the largest proportion of heart failure patients were between 80 and 89 years old (32%), followed by those aged 70 to 79 (30%). Overall, over 90% of patients were 60 years of age or older. The goal of cardiac rehabilitation is to improve physical fitness, reduce the risk of cardiovascular disease, and enhance patients' quality of life.

A comprehensive cardiac rehabilitation program is delivered by an interdisciplinary team of physicians, nurses, physiotherapists, psychologists, nutritionists, and sociologists. Rehabilitation goals include improving circulatory function, mitigating the effects of immobility, optimizing medication therapy, increasing physical activity, and modifying lifestyle. According to the WHO definition, cardiac rehabilitation is a comprehensive therapeutic approach aimed at adapting patients to a new life and restoring their maximum functional capacity. Rehabilitation encompasses many phases, from early in-hospital programs to later outpatient phases. Indications for cardiac rehabilitation include patients after a heart attack, with coronary artery disease, after heart surgery, or with heart failure. A comprehensive cardiac rehabilitation program plays a key role in the secondary prevention of cardiovascular diseases and should be individually tailored to the patient's needs, particularly age-related limitations, comorbidities, and sarcopenia, which is common in older adults. The results of the EMS-PL HF study are intended to provide information on the efficacy and safety of electrical muscle stimulation (EMS) as an adjunct to cardiac rehabilitation in patients aged 60 and older with reduced (HFrEF) and slightly reduced (HFmrEF) ejection fraction. The study was planned to include 45 patients. The study duration per patient was 3 to 4 weeks (9–12 EMS training sessions). Patients were randomly assigned to the following study groups: 1. 15 participants: standard cardiac rehabilitation (control group). 2. 15 participants: standard cardiac rehabilitation + EMS 3 times weekly (intervention group). 3. 15 participants: standard rehabilitation + sham EMS 3 times weekly (sham group). Due to the age of ≥ 60 years and the frequent occurrence of protein deficiency/sarcopenia in this population, all study participants also received a nutritional intervention in the form of supplementation with the protein preparation Protifar (13.2 g protein/day).

Disease or health problem under investigation

ICD-10-GM:
I50.1 - Left ventricular failure

Healthy subjects:
No

Intervention groups, observation groups

Arm 1:
Standard cardiac rehabilitation + EMS three times a week – intervention group.

Arm 2:
Standard rehabilitation + sham EMS three times a week – sham group.

Arm 3:
Standard cardiac rehabilitation – control group.

Endpoints

Primary endpoint:
A significant improvement in ergospirometry.

Secondary endpoint:

Significant improvement in the International Physical Activity Questionnaire (IPAQ), the EQ-5D-5 health questionnaire, and physiotherapy function tests. Improvement in ejection fraction (EF) in echocardiography.

Study design

Study purpose:
therapy

Assignment for intervention:
Controlled, non-randomized study

Control:
Active control (effective treatment of the control group), placebo

Study phase:
III

Study type:
Interventional

Type of covert allocation:
No entry

Blinding:
No

Group design:
Parallel distribution

Type of sequence generation:
No entry

Who is blinded:
No entry

recruitment

Recruitment status:
Recruitment is underway

Reason for discontinuing or withdrawing recruitment:
No entry

Recruitment locations

Recruitment countries:
Poland

Number of testing centers:
Monocentric

Recruitment location(s):
University Hospital Janusz Korczak Voivodeship Specialist Hospital Ltd., Słupsk Slupsk

Recruitment period and number of participants

Planned start of studies:
No entry

Actual start of studies:
May 19, 2025

Planned end of studies:
June 30, 2027

Actual end of studies:
No entry

Planned number of participants:
45

Actual number of participants:
No entry

Inclusion criteria

Gender:
All

Minimum age:
60 years

Maximum age:
no maximum age

Other inclusion criteria:
1. Patients who qualify for inpatient cardiac rehabilitation. 2. Patients aged 60 years and older. 3. Patients who have given their informed consent to participate in the study. 4. Patients with sufficient physical fitness at study entry to complete the exercise program used in the study. 5. Patients diagnosed with reduced (HFrEF) or slightly reduced (HFmrEF) ejection fraction on echocardiogram upon admission to the cardiac rehabilitation unit. 6. Heart failure NYHA class II or III. 7. Patients receiving optimal medical therapy according to current ESC/PTK standards.

Exclusion criteria

1. Inability to put on the muscle stimulation suit. 2. Skin lesions that impair the function of the muscle stimulation suit. 3. Active infection. 4. Pacemaker or defibrillator. 5. Prevention of cardiac rehabilitation. 6. Coronary artery bypass graft surgery with sternotomy. 7. Patient decision. 8. Investigator's decision based on the patient safety assessment: A. Presence of a disease; B. Unnecessary muscle stimulation – CK ≥ 4 times the upper limit of normal (ULN)* *If the CK level is < 4 times the upper limit of normal (ULN), temporary interruption of EMS for 72 hours and an exercise test after a follow-up examination are permissible. Depending on the stimulation intensity, exclusion from stimulation is recommended.

Addresses

Study initiated by (Primary Sponsor)

Pomeranian University in Słupsk
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+48601446102

Fax:
No entry

Contact via email:
damian.sendrowski@upsl.edu.pl

URL of the institution:
https://www.upsl.edu.pl/ *(Link: https://www.upsl.edu.pl/)*

Science-initiated study (IST/IIT):
Yes

Contact for scientific inquiries

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Sources of funding

State or public funding institution, financed by tax revenue (e.g. DFG, BMFTR)

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Phone:
No entry

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Ethics Committee

Address of the Ethics Committee

District Medical Association in Gdansk Bioethical Commission
Sniadeckich 33
80-204 Gdańsk
Poland

Phone:
+49 500 087 739

Fax:
No entry

Contact via email:
bioetyka@komisjabioetyczna.pl

URL of the institution:
http://www.komisjabioetyczna.pl/ *(Link: http://www.komisjabioetyczna.pl/)*

Opinion of the lead ethics committee

Application date to the ethics committee:
May 3, 2024

Ethics Committee processing number:
KB-14/24

Opinion of the Ethics Committee:
Positive review

Date of the vote:
May 7, 2024

Other identification numbers

Other WHO primary registry/data provider ID:
No entry

EudraCT No.:

No entry

UTN (Universal Trial Number):
No entry

EUDAMED No.:
No entry

IPD - Individual Participant Data / Participant-related data

Do you plan to make the participant-related data (IPD) available to other researchers in anonymized form?
No

IPD Sharing Plan:
No entry

Study protocol and other study documents

Study protocols:
No entry

Abstract of the study:
No entry

Further study documents:
No entry

Background literature:
- Damian Sendrowski, Agata Polańska-Szczap, Beata Hus-Budziszewska, Anastasiia Vlaieva, Szymon Markowski, Abraham Carlé-Calo, Dariusz Kozłowski Theoretical and Scientific Underpinnings of Peripheral Muscle Electrostimulation in Cardiac Rehabilitation of the Elderly: A Systematic Review *(Link: https://doi.org/10.20944/preprints202604.1039.v2)*

Related DRKS studies:
No entry

Publication of study results

Planned publication:
2007

Publications/study results:
No entry

Date of first publication of results in a journal:
No entry

DRKS entry published with results for the first time:

No entry

Key Results

Basic Reporting/Results Tables:

No entry

Brief summary of the results:

No entry