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Low-intensity resistance training with moderate blood flow restriction appears safe and increases skeletal muscle strength and size in cardiovascular surgery patients: a pilot study

Submission date
28/01/2021

Recruitment status
No longer recruiting

Registration date
02/02/2021

Overall study status
Completed

Last Edited
29/03/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Generally, patients' muscle size and strength decrease after cardiac (heart) surgery. They usually receive cardiac rehabilitation involving low-intensity aerobic exercise, but this exercise intensity is not enough to increase muscle size and strength. According to the American College of Sports Medicine, resistance training at 60~70% of one repetition maximum is optimal to improve muscle size and strength. However, early after cardiac surgery patients are often unable to perform such high-intensity resistance training.
The new KAATSU training moderately restricts blood flow by compressing the proximal portion of the lower or upper extremities with a specially-designed cuff. It is a well-established method to increase muscle size and strength in athletes and healthy people through short-term and low-intensity training (20~30% of one repetition maximum). Therefore, the aim of this study is to determine whether low-intensity KAATSU resistance training can safely increase muscle size and strength in patients undergoing cardiac open surgery.

Who can participate?
Inpatients receiving cardiac open surgery between April 2017 and June 2020

What does the study involve?
The study compares muscle size and physical function change before, early after cardiac surgery, and after 3 months between a group who receive general cardiac rehabilitation and a group receiving low-intensity KAATSU resistance training added on to general cardiac rehabilitation. To evaluate the safety of KAATSU resistance training in cardiac surgery patients, the researchers monitor blood biochemistry at the start of the study and after 3 months. Medical staff carefully monitor patients for adverse side effects.

What are the possible benefits and risks of participating?
If low-intensity KAATSU resistance training safely increases muscle size and strength in cardiac surgery patients, it will be an effective method for cardiac rehabilitation. However, cardiac

surgery involves a risk of deep vein thrombosis and KAATSU resistance training has a risk of adverse side effects, so participants start at very low-intensity (under 10% of one repetition maximum) and increase intensity in a stepwise manner, and medical staff monitor them during the KAATSU resistance training.

Where is the study run from?
Dokkyo Medical University Hospital (Japan)

When is the study starting and how long is it expected to run for?
October 2015 to June 2020

Who is funding the study?
JSPS KAKENHI (Japan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
27074

Study information

Scientific Title
Low-intensity resistance training with moderate blood flow restriction appears safe and increases skeletal muscle strength and size in cardiovascular surgery patients: a pilot study

Study objectives
The purpose of the present study is to determine if low-intensity KAATSU resistance training can safely increase muscle strength and size in patients undergoing cardiac open surgery. It is hypothesized that low-intensity KAATSU resistance training also provides beneficial effects in cardiovascular surgery patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/10/2015, The Regional Ethics Committee of Dokkyo Medical University Hospital (880 Kitakobayashi, Mibumachi, Shimotsuga-gun, Tochigi 321-0293, Japan; +81 (0)282 86 1111; email: not provided), ref: 27074

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Cardiac open surgery

Interventions
Cardiac patients are randomised using the envelope method to the control group (n=10) and the KAATSU resistance training group. All patients receive a standard aerobic cardiac rehabilitation program. The KAATSU resistance training group additionally execute low-intensity leg extension and leg press exercises with moderate blood flow restriction twice a week for 3 months.

Intervention Type
Behavioural

Primary outcome measure
1. Muscle volume measured using a multi-frequency bioelectrical impedance analyzer (BIA) at baseline, 5-7 days after cardiac surgery, and after 3 months
2. The anterior thigh muscle thickness measured using ultrasound at baseline, 5-7 days after cardiac surgery, and after 3 months
3. Handgrip strength during maximal voluntary isometric contraction measured using a handgrip dynamometer at baseline, 5-7 days after cardiac surgery, and after 3 months
4. Knee extensor strength during maximal voluntary isometric contraction measured using a digital handheld dynamometer at baseline, 5-7 days after cardiac surgery, and after 3 months
5. Walking speed computed as the time needed to walk 4 m at a habitual pace at baseline, 5-7 days after cardiac surgery, and after 3 months

Secondary outcome measures
1. Left ventricular ejection fraction calculated using the Simpson method based on two-dimensional images measured using cardiovascular ultrasound at baseline
2. Hemoglobin A1, albumin, brain natriuretic peptide, creatinine, creatine phosphokinase, high-sensitivity C-reactive protein, prothrombin time-international normalized ratio, and D-dimer (only for KAATSU resistance training group) obtained from routine biochemical analysis performed in the hospital's clinical laboratory at baseline and after 3 months
3. Body composition including body fat volume, % body fat, extracellular water, and total body water, measured using BIA at baseline, 5-7 days after cardiac surgery, and after 3 months
4. Circulatory hemodynamics monitored using a hemodynamics analyzer during hospitalization
5. Adverse side events including dizziness, subcutaneous hemorrhage, petechial hemorrhage, drowsiness, numbness, nausea, itchiness, and new deep vein thrombosis monitored by medical staff during KAATSU resistance training

Overall study start date
13/10/2015

Completion date
30/06/2020

Eligibility

Key inclusion criteria
Of the inpatients receiving cardiac open surgery between April 2017 and June 2020, a total of 25 patients, who met the following criteria, were recruited to participate in the study:
1. Able to perform the preoperative evaluation of leg extension strength
2. Able to perform postoperative cardiac rehabilitation program consisting of aerobic exercise
3. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Patients are assigned either to a control group (n=10) or a KAATSU resistance training group (n=11)

Total final enrolment
21

Key exclusion criteria
1. Serious perioperative complications such as pneumonia, instability of hemodynamics, heart failure and cardiac arrhythmias
2. Emergency surgery cases, dialysis patients, and patients who could not walk independently, and perform resistance exercise
3. Current neurological disorders or previous cerebral vascular accident with residual neurological deficit significant enough to limit exercise
4. Malignant tumor, past fracture of the hip, pelvis, or femur, varicose veins, family or personal history of deep vein thrombosis, family or personal history of pulmonary embolism
5. Patients with pacemaker implantation who can not receive BIA methods

Date of first enrolment
01/02/2017

Date of final enrolment
15/03/2017

Locations

Countries of recruitment
Japan

Study participating centre
Dokkyo Medical University
Heart center
Kitakobayasi 880
Shimotsuga-gun
Mibumachi
Tochigi
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321-0293

Sponsor information

Organisation
Dokkyo Medical University

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Sponsor type
University/education

Website
http://www.dokkyomed.ac.jp/en/520.html

ROR
https://ror.org/05k27ay38

Funder(s)

Funder type
Research organisation

Funder Name
Japan Society for the Promotion of Science (JSPS) KAKENHI

Alternative Name(s)
KAKENHI, , Gakushin, JSPS KAKEN, JSPS Grants-in-Aid for Scientific Research, JSPS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Japan

Results and Publications

Publication and dissemination plan
The researchers intend to publish in the Journal of Clinical Medicine. No additional documents are available.

Intention to publish date
01/02/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the local ethics committee restricts the release of patients' data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	outcome results	02/02/2023	29/03/2023	Yes	No