

# 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

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| <b>Registration date</b><br>02/02/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>29/03/2023       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> 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?  
Dr Toshiaki Nakajima  
nakat@dokkyomed.ac.jp

## 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**  
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

## Study type(s)

Treatment

## 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(s)

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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

Japan

321-0293

## Sponsor information

**Organisation**

Dokkyo Medical University

**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, JSPS KAKEN, JSPS Grants-in-Aid for Scientific Research, Gakushin, , Nihon Gakujutsu Shinkō Kai, JSPS

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

Japan

## **Results and Publications**

### **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**

| <b>Output type</b>              | <b>Details</b>  | <b>Date created</b> | <b>Date added</b> | <b>Peer reviewed?</b> | <b>Patient-facing?</b> |
|---------------------------------|-----------------|---------------------|-------------------|-----------------------|------------------------|
| <a href="#">Results article</a> | outcome results | 02/02/2023          | 29/03/2023        | Yes                   | No                     |