

# Effects of physiological induced changes in afterload of the left ventricle on the strain-volume loop

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON45478

### Source

ToetsingOnline

### Brief title

Strain-volume loop after physiological changes in afterload

### Condition

- Heart failures

### Synonym

cardiac function

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Fysiologie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cardiac function, Echocardiography, Hemodynamics, Strain-volume loop

## Outcome measures

### Primary outcome

The primary study parameter will be the slope of the systolic strain-volume relation ( $S_{slope}$ )

### Secondary outcome

The secondary parameters will be the early systolic strain ( $*_{ES}$ ), peak strain (peak  $*$ ) and the dissociation between the systolic and diastolic strain-volume relation during early diastole (UNCOUP\_ED) and late diastole (UNCOUP\_LD).

## Study description

### Background summary

Both acute and chronic changes of the preload and afterload of the heart influence the hemodynamics, structure and function of the ventricles. In case of as well acute as chronic changes of the loading condition of the ventricle wall, the ventricle tries to correct the changed loading condition by changing its function (contractility) or structure (wall thickness or dilatation) of the ventricle wall.

Introduction of speckle tracking echocardiography allows measurement of the ventricular deformation (i.e. strain). By combining temporal echocardiographic measurements of strain (functional) and volume (structure) of the left ventricle a strain-volume loop can be constructed. Using this strain-volume loop allows us to detect changes in hemodynamic conditions of the ventricles. In a previous study we found that chronic changes in afterload result in changes in the strain-volume loop. To further assess the usability of this new technique we aim to assess the effects of acute changes in afterload on the strain-volume loop, by increasing as well as decreasing the afterload of the heart.

In addition to this we know that strain is influenced by increasing age, therefore we also will assess the influence of age on the observed changes in the strain-volume loop to determine whether age influences the applicability of

this technique.

## **Study objective**

Our primary aim is to determine whether the changes of the strain-volume loop can be used to detect an acute change of the afterload (and thus hemodynamics) of the heart in healthy subjects.

Our secondary aim is to determine whether age influences the observed changes of the strain-volume loop.

## **Study design**

In this exploratory study, 40 healthy subjects will be assessed prior to and after an intervention through a non-invasive echocardiographic assessment

## **Intervention**

To induce the changes in afterload we will use two different interventions:

- To reduce the afterload (and preload) we will use vasodilative medication (vasodilator; nitroglycerine), which will primarily reduce the peripheral vascular resistance.
- To increase the afterload we will use anti gravity jeans to occlude the blood supply of the legs for 2 minutes (transient atrial occlusion), which will cause an increase in the peripheral vascular resistance.

## **Study burden and risks**

During this study, subjects are scheduled to visit the department of physiology only once. During the measurements an echocardiographic assessment will be performed prior to and during a stimulus which increases (anti gravity jeans) or decreases (nitroglycerine) the afterload. All measurements are non-invasive and without any added risks for the subject. The risks of both interventions (the antigravity jeans, and a low dose of sublingual administered nitroglycerine) are negligible.

## **Contacts**

### **Public**

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## **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Age (between 18 and 30 or above 60)  
voluntary participation

### **Exclusion criteria**

History of cardiovascular diseases (coronary disease, hypertension, collapse, cardiac failure, peripheral vascular disease)

Diabetes mellitus

Use of medication that influences the cardiovascular system

Contraindication to use nitroglycerin (hypersensitivity or usage of medication that interacts with nitroglycerin)

## **Study design**

## Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 28-08-2017

Enrollment: 40

Type: Actual

## Ethics review

Approved WMO

Date: 11-04-2017

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL60656.091.17

## Study results

Date completed:	18-04-2019
Actual enrolment:	35