

# The effect of ventricular unloading on the T-wave

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The main objective in this study is to determine whether there is an effect of acute unloading of the left ventricle on the ECG, in particular the T-wave.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cardiac disorders, signs and symptoms NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39221

### Source

ToetsingOnline

### Brief title

UNLOAD-T study

### Condition

- Cardiac disorders, signs and symptoms NEC

### Synonym

ECG, T-wave

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** AMC/AMR

### Intervention

**Keyword:** Impella, mechano-electrical feedback, repolarization, T-wave

## Outcome measures

### Primary outcome

Change of BSM integral maps of the QRST- and STT-interval

### Secondary outcome

Several other variables associated with the T-wave and derivable from the BSM.

These variables include the non-dipolar content of the integral maps, T-wave amplitude, T-wave duration, T-peak to T-end interval (TpTe), QRS duration, QT-interval, isochrones in the body surface map, QRS integral map, and dispersion in these values.

## Study description

### Background summary

The electrocardiogram (ECG) is the most important diagnostic tool in cardiology, measuring electrical activity in the heart. T-wave abnormalities are associated with e.g. ischemia, repolarization disorders and arrhythmias which may lead to sudden cardiac death. The (patho)physiological background of the T-wave and its alterations however, is not beyond debate. Many studies have been conducted to examine the exact genesis of the T-wave. Notwithstanding that multiple factors may affect the morphology of the T-wave, the majority of these studies are solely focused on the dispersion in repolarization of the action potential. The heart however, is a contracting and relaxing muscle which suggests that, beside electrical factors, mechanical factors may be of importance as well. Examination of the effect of cardiomechanics on the morphology of the T-wave may contribute to a better understanding of T-wave genesis and consequently an improvement of the diagnostics of repolarization disorders and the associated risk for arrhythmias. In order to elucidate the effect of cardiomechanics on the ECG in the in vivo human heart, we selected a moment in which an abrupt change in ventricular work load occurs, and structural remodelling is absent. In the catheterisation lab, acute unloading of the heart takes place during impella guided percutaneous coronary interventions. Therefore we selected this moment to make body surface maps (BSMs; multiple lead ECGs) recordings in order to assess whether any changes occur, and whether mechanoelectrical feedback plays a role in vivo

## Study objective

The main objective in this study is to determine whether there is an effect of acute unloading of the left ventricle on the ECG, in particular the T-wave.

## Study design

Observational

## Study burden and risks

The PCI procedure will be extended with 15-20 minutes extra time (10 minutes for preparation and application of electrodes, plus 5-10 minutes for the BSM measurements). This includes one extra stepwise increase in pump settings and one stepwise decrease. This all is not accompanied by extra risks for the patient. In some cases shaving of the thorax is necessary to obtain good contact of electrodes with the skin. The electrodes of the BSM system might cause skin reactions such as irritation and itching. There will be no extra fluoroscopy time due to measurements. The BSM electrode strips are radio-translucent and do not influence the PCI procedure.

## Contacts

### Public

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105 AZ  
NL

### Scientific

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105 AZ  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients undergoing an elective percutaneous coronary intervention (PCI) with a supportive Impella placement.

### Exclusion criteria

Unstable rhythm: atrial fibrillation (AF); Frequent occurrence of ventricular or atrial extra systoles (VES, AES); Ventricular tachycardias (VTs).

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 02-05-2013

Enrollment: 25

Type: Actual

## Ethics review

Approved WMO

Date:	19-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL37678.018.12