

# Creatine kinase and blood pressure response

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In this study, we will prospectively assess the association between serum CK and response to standard antihypertensive drugs (calcium blockers or monotherapy with other antihypertensive drugs according to the policy of the general practitioner).

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Vascular hypertensive disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON37003

### Source

ToetsingOnline

### Brief title

Creatine kinase and blood pressure response

### Condition

- Vascular hypertensive disorders

### Synonym

high blood pressure, Hypertension

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** Creatine kinase, Hypertension, Treatment failure

## Outcome measures

### Primary outcome

The difference in blood pressure response after 3 weeks of treatment in relation to baseline serum CK.

### Secondary outcome

The difference between serum CK activity at baseline and after 3 weeks of treatment with antihypertensive drugs.

## Study description

### Background summary

Failure of hypertension treatment is a major clinical issue. We have reported evidence that creatine kinase (CK) increases blood pressure through greater sodium retention and cardiovascular contractility, by rapidly providing ATP for these functions. Furthermore, we found in a cross-sectional setting that CK was the main predictor of treatment failure (adjusted OR 3.7; 95% CI 1.2 to 10.9) in the population, independent of age, sex, BMI, fasting glucose, ethnicity, or education level.

### Study objective

In this study, we will prospectively assess the association between serum CK and response to standard antihypertensive drugs (calcium blockers or monotherapy with other antihypertensive drugs according to the policy of the general practitioner).

### Study design

Observational study

### Study burden and risks

The extra burden for the participant besides the regular first line patient care is the draw of 2 extra tubes of blood.

The antihypertensive treatment and diagnostic examinations (blood draw, EKG, urine analysis) are all clinical standards within first line care.

Venapunction may induce a vasovagal collapse. We expect little side effects for the standard first line treatment. Side effects that may occur with calcium blockers are headache, oedema, redness of the face, constipation, and fatigue.

Then the medication will be switched to another drug in accord with the general practitioners protocol.

## 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

Ambulatory adult subjects age 18-60 years, with newly detected hypertension stage I and II

in primary care (SBP/DBP  $\geq$  140/90 and SBP/DBP  $<$  180/110 on at least two consecutive visits), after three days of rest, otherwise healthy, without clinical or laboratory evidence of muscle damage.

## Exclusion criteria

No rest during the last 3 days, treated hypertension, severe (SBP  $\geq$  180 mm Hg) hypertension, secondary hypertension, (history of) cardiovascular disease including TIA and stroke, myocardial infarction, angina, BMI  $\geq$  30 kg/m<sup>2</sup>, diabetes mellitus, lipid spectrum abnormalities, thyroid, kidney, or liver abnormalities; CK-increasing drugs including statins; neuromuscular or endocrine disorders; vasculitis; HIV infection; infectious hepatitis.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL  
Recruitment status: Will not start

Enrollment: 100

Type: Anticipated

## Ethics review

Approved WMO

Date: 25-07-2012

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	NL40748.018.12