# Utrecht Health Project - Utrecht Cardiovascular Cohort (UHP-UCC)

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Objectives: 1. To what extent does the CVRM risk profile and co-morbid conditions differ between individuals with (UCC-SMART) and without (UHP-UCC) symptoms of heart failure, but with similar levels of echocardiographic structural- and functional...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Heart failures |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON55070

**Source**
ToetsingOnline

**Brief title**
UHP-UCC

### Condition

- Heart failures
- Nephropathies
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
atherosclerosis, cardiovascular disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** UMC Utrecht

## Intervention

**Keyword:** atherosclerosis, cardiovascular disease, prevention

## Outcome measures

### Primary outcome

For the 1st research question: To what extent does the CVRM risk profile and co-morbid conditions differ between individuals with (UCC-SMART) and without (UHP-UCC) symptoms of heart failure, but with similar levels of echocardiographic structural- and functional measurements?

The main outcome is: presence (and absence) of symptomatology belonging to potentially heart failure combined with referral to UMC Utrecht, assessed with the Heart Failure symptoms questionnaire.
The main determinants are: CVRM profile and co-morbidity
Potential confounders: age, sex, level of left ventricular dimensions and ejection fraction.

For the 2nd research question: To what extent does the CVRM profile and co-morbid conditions differ between individuals without cerebral ischemic symptoms (UHP) from those with symptoms of cerebral ischemia (UCC-SMART), given a similar level of carotid structural and functional values?
The main outcome is: presence (and absence) of symptomatology belonging cerebral ischemia based on questionnaire data combined with referral to the UMC Utrecht
The main determinants are: CVRM profile and co-morbidity

Potential confounders: age, sex, level of carotid atherosclerosis.

For the 3rd research question: To what extent does Ideal Cardiovascular Health, assessed by 7 cardiovascular health metrics defined by the American Heart Association, differ between those with (UCC-SMART) and without (UHP-UCC) symptoms of CVD, but with similar levels of cardiac, aortic and carotid structural abnormalities?
The main outcome is: presence (and absence) of symptomatology belonging vascular disease based on questionnaire data combined with clinical information from GP and/or UMC Utrecht
The main determinants are: CVRM profile and co-morbidity
Potential confounders: age, sex, level of subclinical disease of the heart, the carotid artery and the aorta.

For the 4th research question: To what extent does the CVRM risk profile and co-morbid conditions differ between diabetic patients treated by the general practitioner (UHP-UCC) from those treated by the specialist (UCC-SMART), given similar level of glycemic control and level of subclinical vascular disease) ?
The main outcome is: diabetics treated by the GP or in the UMC Utrecht
The main determinants are: CVRM profile and co-morbidity
Potential confounders: age, sex, level of glycaemic control and subclinical vascular disease (cardiac/carotid/aorta)

For the 5th research question: To what extent does the CVRM risk profile and

co-morbid conditions differ between hypertensive patients treated by the

general practitioner (UHP-UCC) from those treated by the specialist

(UCC-SMART), given similar level of blood pressure control?

The main outcome is: hypertension treated by the GP or in the UMC Utrecht

The main determinants are: CVRM profile and co-morbidity

Potential confounders: age, sex, level of blood pressure.

### Secondary outcome

n.v.t.

## Study description

### Background summary

The Utrecht Health Project (UHP) is an ongoing primary care-based cohort study among patients enlisted with academic general practice centers affiliated with the Julius Center, University Medical Center Utrecht, the Netherlands. Patients from a recently developed residential area, Leidsche Rijn, suburb of Utrecht, are invited to come in for an *individual health profile* (IHP). The study is described more extensively elsewhere.2 In short, all participants receive a general health questionnaire, and information is obtained on medical history, current medication use, and lifestyle. Height and weight are measured and cholesterol and glucose are determined. Blood pressure is measured on the dominant arm with an Omron M4 device. A blood sample is stored in the UMC Utrecht Biobank. Follow-up is performed through linkage with the general practitioner records. Inclusion of participants in the UHP started in 2000. The UHP has been approved by the UMC Utrecht Institutional Review Board (protocol 99/240). Informed consent is obtained from all participants. Since 2014, harmonization of UCC-CVRM and UHP has already performed in terms of measurements and informed consent.
UCC-CVRM provides an infrastructure for uniform registration of guideline based cardiovascular information embedded in routine care and for systematic follow-up of these patients.1 Furthermore, UCC-CVRM was designed to be linked with cohort information from the UHP. The notion is that the inclusion of the full spectrum of subjects from healthy to severely diseased expands generation of knowledge (scientific evidence) on the development of the various phases of vascular disease, the main drivers of the change from asymptomatic to symptomatic conditions, and the consequences in terms of referral, use of

general practice and hospital health care facilities, morbidity and mortality. With the additional data collection in the UHP-UCC project in close collaboration with UCC-SMART and UCC-CVRM, we now describe a limited number of dedicated research projects that constitute part of the rationale for this submission. These questions closely fit within the research priorities of the Leidsche Rijn Academic Julius Health Care Centers and the UMC Utrecht Center of Circulatory Health. Yet, we realize that the data that will be collected with the information of the combined cohorts could and will address many more research questions once the data has been collected. As such, the structure needed for this proposal serves a wider scope than the research questions as described below.

**Study objective**

Objectives:
1. To what extent does the CVRM risk profile and co-morbid conditions differ between individuals with (UCC-SMART) and without (UHP-UCC) symptoms of heart failure, but with similar levels of echocardiographic structural- and functional measurements?
2. To what extent does the CVRM profile and co-morbid conditions differ between individuals without cerebral ischemic symptoms (TIA or ischemic cortical stroke) (UHP) from those with symptoms of cerebral ischemia (UCC-SMART), given a similar level of carotid structural- and functional measurements?
3. To what extent does Ideal Cardiovascular Health, assessed by 7 cardiovascular health metrics defined by the American Heart Association, differ between those with (UCC-SMART) and without (UHP-UCC) symptoms of CVD, but with similar levels of cardiac and carotid structural abnormalities?
4. To what extent does the CVRM risk profile and co-morbid conditions differ between patients treated by the general practitioner (UHP-UCC) from those with diabetes treated by the specialist (UCC-SMART), given similar level of glycaemic control and level of subclinical vascular disease?
5. To what extent does the CVRM risk profile and co-morbid conditions differ between hypertensive patients treated by the general practitioner (UHP-UCC) from those treated by the specialist (UCC-SMART), given similar level of blood pressure control?

**Study design**

Study design: A prospective cohort study.

**Study burden and risks**

At home, participants are asked to complete questionnaires on a variety of topics (either on paper or through an online approach) (see table 1). Additional measurements include a blood pressure measurement, length, weight, waist circumference, a 12 lead ECG, carotid, cardiac and abdominal ultrasound,

blood and urine sample. Apart from the time -consuming burden of the appointments, the questionnaires, ECG, blood pressure measurements, ultrasound examinations and blood sampling are not associated with any considerable risk. The general idea is that overall UHP-UCC participants benefit from all measurements because their cardiovascular health status will be measured in detail and the results including treatment advice will be sent to the concerning general practitioner. Therefore, potentially (more) tailored therapy strategy can be effectuated.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

• Being a participant of the Utrecht Health Project.
• Having a signed written UHP informed consent, allowing follow-up through

linkage with registries and sharing information across medical professionals.
• Indicated in UHP informed consent to be interested in participating in further research.
• Having had blood samples stored in the UHP biobank.

### Exclusion criteria

• Receiving major (cardiovascular) surgery, and/or revascularisation therapy and/or transplantation treatment within 3 months after enrolment.
• Below the age of 40 years and above 84.
• Not willing to give written informed consent for UHP-UCC.
• Not allowing incidental findings to be reported.
If the patient gives broad consent, the patient allows to be informed about findings that may be important for him/her. If the patient and/or his representative refuse to agree on this, the patient will not be included.

## Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 04-01-2021 |
| Enrollment: | 800 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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| Date: | 20-01-2021 |
| Application type: | First submission |

Review commission: METC NedMec

# 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 | NL74683.041.20 |