

# The role of hormones in acute coronary syndrome (heart attack)

<b>Submission date</b> 08/12/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/12/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/08/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims

Revised for an 18-year-old audience: Estrogens help protect the heart in the early stages of life. However, a specific type of estrogen called 17 $\beta$ -estradiol (E2) can speed up the progression of a condition called atherosclerosis, which involves the buildup of plaque in the arteries.

Who can participate?

Adult men and women diagnosed with acute coronary syndrome, admitted to hospital, who received catheter-based coronary reperfusion when appropriate.

What does the study involve?

We're studying the levels of certain hormones (E2, total testosterone [T], and dehydroepiandrosterone-sulfate [DHEA-S]) when patients are admitted to the hospital. We're also looking at their relationship with other things like oxidized low-density lipoproteins (oxDL), extracellular superoxide dismutase (ecSOD), high-sensitive C-reactive protein (CRP), white blood cell counts (WBC), and cardiac enzymes (creatinine kinase [CK], the CK Muscle-Brain fraction [CK-MB], and high-sensitive troponin T [hsTnT]). This assessment is done within two hours after a procedure to clear blockages in the heart arteries, called coronary revascularization, which can involve angioplasty with or without stenting.

We're using something called the SYNTAX score to measure how severe the coronary disease is based on the results of a test called coronary angiography.

We're following these patients for a year and checking CRP, oxLDL, and ecSOD again. We're also keeping track of any bad events like another heart attack (reinfarction), additional procedures to clear arteries (revascularizations), and deaths.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Medical University of Sofia (Bulgaria)

When is the study starting and how long is it expected to run for?

Who is funding the study?  
Medical University of Sofia (Bulgaria)

Who is the main contact?  
Dr Niya Semerdzhieva, niaemilova@yahoo.com

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

35D/2012

## Study information

### Scientific Title

Significance of dehydroepiandrosterone-sulfate and gonadal sex hormones in acute coronary syndrome - sex-based differences

### Acronym

SHACS

### Study objectives

Sex steroids (dehydroepiandrosterone-sulfate [DHEA-S], 17-beta estradiol [E2], total testosterone [T]) in the acute phase of coronary syndrome are associated with the peak levels of oxidized low-density lipoproteins (oxLDL), extracellular superoxide dismutase (ecSOD), high-sensitive C-reactive protein (CRP), white blood cell counts (WBC) and cardiac enzymes (creatinine kinase [CK], the CK Muscle-Brain fraction [CK-MB], and high-sensitive troponin T [hsTnT]) and with adverse events - a year after ACS.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 30/05/2012, Ethics committee of Medical University (15 Acad Ivan Geshov str., Sofia, 1431, Bulgaria; +359 2 9152157; atanasova@mu-sofia.bg), ref: 81/30/05/2012

### **Study design**

Single-center cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

### **Health condition(s) or problem(s) studied**

Acute coronary syndrome

### **Interventions**

Sex steroids (E2, total testosterone [T]) and DHEA-S, oxidized low-density lipoproteins, high-sensitive C-reactive protein (CRP), white blood cell counts (WBC), and cardiac enzymes (creatinine kinase [CK], the CK Muscle-Brain fraction [CK-MB], and high-sensitive troponin T [hsTnT]) were measured at admission. The inflammatory and myocardial injury markers were evaluated within two hours after coronary revascularization. The SYNTAX score gauged coronary disease severity from coronary angiography results.

### **Intervention Type**

Other

### **Primary outcome measure**

1. Oxidized low-density lipoproteins (oxLDL), high-sensitive C-reactive protein (hsCRP), white blood cell counts (WBC), and cardiac enzymes (creatinine kinase [CK], Muscle-Brain fraction of CK

[CPK-MB], high-sensitive troponin T [hsTnT]) were evaluated in plasma obtained within two hours of coronary angiography (CAG)

2. Coronary disease severity, measured using SYNTAX score after CAG

3. Total 17 $\beta$ -estradiol [E2], total testosterone [T], dehydroepiandrosterone-sulfate [DHEA-S] measured using blood samples drawn 48 hours after symptom onset

### **Secondary outcome measures**

Patient information on obesity, diabetes mellitus and incidence of revascularizations, reinfarctions and deaths after one- year follow up measured using patient records.

### **Overall study start date**

01/07/2011

### **Completion date**

30/06/2014

## **Eligibility**

### **Key inclusion criteria**

Adult men and women admitted to hospital with acute coronary syndrome.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

35 Years

### **Upper age limit**

95 Years

### **Sex**

Both

### **Target number of participants**

200

### **Total final enrolment**

175

### **Key exclusion criteria**

Acute infectious disease, any diagnosed neoplastic disease; fracture, physical trauma or surgical procedure a month before and after the inclusion period and at the end of the follow-up.

### **Date of first enrolment**

01/05/2011

### **Date of final enrolment**

30/06/2014

## **Locations**

### **Countries of recruitment**

Bulgaria

### **Study participating centre**

**University Hospital 'Alexandrovska'**

1 Georgi Sofyiski street

Sofia

Bulgaria

1431

## **Sponsor information**

### **Organisation**

Medical University of Sofia

### **Sponsor details**

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### **Sponsor type**

University/education

### **Website**

<https://mu-sofia.bg>

### **ROR**

<https://ror.org/01n9zy652>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Medical University Sofia

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Bulgaria

Results and Publications

Publication and dissemination plan

Three articles published. Planned publications in a high-impact peer-reviewed journal.

Intention to publish date

30/01/2024

Individual participant data (IPD) sharing plan

Individual participant data - available on request; contact: Dr. Niya Emilova Semerdzhieva, e-mail : niaemilova@yahoo.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			13/12/2023	No	No
<a href="#">Results article</a>		13/06/2025	18/06/2025	Yes	No
<a href="#">Results article</a>		19/08/2025	20/08/2025	Yes	No