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

Submission date 08/12/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 18/12/2023	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/06/2025	**Condition category** Circulatory System	[_] 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 17β-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 (creatine 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

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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 (creatine 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 (creatine 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 (creatine 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 17β-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

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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?
Protocol file			13/12/2023	No	No
Results article		13/06/2025	18/06/2025	Yes	No