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The effect of a single dose of SGLT2 inhibitor, empagliflozin, on oxidative stress in patients undergoing elective coronary angiography

Submission date
10/10/2025

Recruitment status
No longer recruiting

Registration date
13/10/2025

Overall study status
Completed

Last Edited
15/10/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate whether a single dose of the drug empagliflozin, given before a planned (elective) coronary angiography, can reduce oxidative stress in patients without diabetes. Oxidative stress plays a key role in the development and progression of cardiovascular disease. While empagliflozin is usually used to treat diabetes and heart failure, recent findings suggest it may also have antioxidant effects. This study will assess those effects in a clinical setting.

Who can participate?
Adults aged 18 years or older who are scheduled to undergo elective coronary angiography are eligible to participate in the study. Participants must be able to understand the study procedures and provide written informed consent. People with diabetes, advanced kidney disease, active cancer, autoimmune disease, or recent heart attacks are not eligible.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive a single 10 mg dose of empagliflozin before the coronary angiography; the other group will receive standard care. Blood samples will be collected before and after the procedure to measure markers of oxidative stress, DNA damage, and protein glycosylation. The study is double-blinded, meaning neither the participants nor the investigators performing analyses will know who received the drug.

What are the possible benefits and risks of participating?
There is no direct benefit to participants. However, the findings may help researchers better understand the antioxidant effects of empagliflozin and improve future patient care. Risks are minimal, as the drug is already approved and widely used in clinical practice, and blood samples are taken using standard procedures.

Where is the study run from?
The study is conducted at the Department of Cardiology, General Hospital Dr Josip Bencevic, Slavonski Brod, Croatia, in collaboration with several research institutes in Zagreb.

When is the study starting and how long is it expected to run for?
The study began in September 2023 and is expected to run for approximately 12 months.

Who is funding the study?
1. Croatian Science Foundation
2. European Union – NextGenerationEU Program

Who is the main contact?
Dr Katica Cvitkusic Lukenda, Department of Cardiology, General Hospital Dr Josip Bencevic, Slavonski Brod, Croatia, Katica.Cvitkusic-lukenda@bolnicasb.hr, kclukenda@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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Study information

Scientific Title
Empagliflozin and oxidative stress in non-diabetic patients undergoing coronary angiography

Study objectives

The aim of this study is to determine whether a single dose of the SGLT2 inhibitor empagliflozin, administered before elective diagnostic coronary angiography, can reduce oxidative stress in patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 07/09/2023, Ethics Committee of General Hospital Dr. Josip Bencevic (Andrije Stampara 42, Slavonski Brod, 35000, Croatia; +385 35 201 610; bolnicasb@bolnicasb.hr), ref: URBROJ: 04000000/23-65

2. approved 23/10/2023, Ethics Committee of the Institute for Medical Research and Occupational Health (Ksaverska cesta 2, Zagreb, 10001, Croatia; +385 1 458 2500; jmacan@imi.hr), ref: URBROJ: 100-21/23-12

3. approved 30/11/2023, Bioethics Committee of the Ruder Boskovic Institute (Bijenicka cesta 54, Zagreb, 10000, Croatia; +385 1 456 0950; stojkov@irb.hr), ref: BROJ: BEP-5968/2-2023.lu

Study design
Prospective randomized double-blind controlled parallel-group interventional study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Coronary Artery Disease
Oxidative Stress
Angiography, Coronary
Sodium-Glucose Transporter 2 Inhibitors

Interventions
Experimental group: Single oral dose of empagliflozin 10 mg administered approximately 2 hours before elective coronary angiography, in addition to standard premedication (e.g., anxiolytics).
Control group: Standard premedication care without empagliflozin.
Both groups:
Venous blood samples were collected at three time points:
Baseline (before coronary angiography),
4 hours after coronary angiography,
24 hours after coronary angiography.
Total Antioxidant Capacity (TAC) – measured at all three time points (baseline, 4h, 24h)
DNA damage assessment via alkaline comet assay – performed at all three time points
IgG and total plasma protein N-glycosylation profiling – performed at baseline and 24 hours after the procedure
Routine biochemical parameters: serum creatinine, estimated glomerular filtration rate (eGFR), high-sensitivity troponin I (hsTnI), and high-sensitivity C-reactive protein (hsCRP) – measured at baseline and 24 hours after coronary angiography.

Randomization method: Simple randomization using a computer-generated list, with allocation performed by an independent third party.
Duration of intervention: Single administration.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Empagliflozin

Primary outcome(s)
Change in oxidative stress levels, measured directly using Total Antioxidant Capacity (TAC) at baseline, 4, and 24h, and indirectly using a Comet assay at baseline, 4, and 24h, and N-glycan profiling at baseline and 24 hours after coronary angiography

Key secondary outcome(s))
Changes in biochemical markers, including serum creatinine, estimated glomerular filtration rate (eGFR), high-sensitivity cardiac troponin I (hs-TnI), and high-sensitivity C-reactive protein (hsCRP), were measured using standard biochemical methods at baseline and 24 hours after coronary angiography

Completion date
23/01/2024

Eligibility

Key inclusion criteria
1. Scheduled for elective coronary angiography
2. Able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 years

Upper age limit
85 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Estimated glomerular filtration rate (eGFR) < 30 ml/min/1.73 m²
2. New York Heart Association (NYHA) class IV heart failure
3. Recent acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI) within the past 6 months
4. Active malignancy
5. Inflammatory or autoimmune disease
6. Chronic use of SGLT2 inhibitors
7. Diagnosed diabetes mellitus
8. Heart failure with reduced ejection fraction (HFrEF)
9. Life expectancy less than 12 months

Date of first enrolment
05/10/2023

Date of final enrolment
23/01/2024

Locations

Countries of recruitment
Croatia

Study participating centre
General Hospital Dr. Josip Bencevic
Andrije Stampara 42
Slavonski Brod
Croatia
35000

Sponsor information

Organisation
General Hospital Slavonski Brod

Funder(s)

Funder type
Government

Funder Name
Hrvatska Zaklada za Znanost

Alternative Name(s)
Croatian Science Foundation, The Croatian Science Foundation, HRZZ

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Croatia

Funder Name
NextGenerationEU

Alternative Name(s)
Next Gen EU, European Union Recovery Instrument, Next Generation EU, NGEU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be available upon request from Katica Cvitkusic Lukenda, MD, PhD, Katica.Cvitkusic-lukenda@bolnicasb.hr, kclukenda@gmail.com.
- Type of data that will be shared: Participant-level data related to oxidative stress markers (TAC, Comet assay, N-glycan profiling), biochemical results, basic demographic and clinical parameters (e.g. age, sex, comorbidities, anthropometry, blood pressure).
- Timing for availability: Data will be made available upon reasonable request, following publication of the primary results.
- Consent: Informed consent included a statement that data may be used for future research purposes and that all shared data will be anonymized.
- Anonymization: All shared data will be fully anonymized, with no personally identifiable information included.
- Ethical or legal restrictions: No additional restrictions beyond standard anonymization and

ethical use of data.
- Additional comments: We are committed to transparency and collaboration and will consider data sharing requests that align with ethical standards and the scope of the original consent.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	CONSORT flow diagram		15/10/2025	No	No
Other files	Informed Consent Form – Croatian version		15/10/2025	No	No
Other files	Informed Consent Form – English version		15/10/2025	No	No
Other files	SPIRIT timeline		15/10/2025	No	No