**Study protocol (TRACT trial 2)**

# Single-Catheter Technique and Dual-Catheter Technique for Transradial Coronary Angiography

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**Title:** Single-catheter technique and dual-catheter technique for transradial coronary angiography

**Aim of the study**: The aim of the following study is to assess the efficacy and safety of catheters dedicated for SCT and compare the results with catheters used in standard DCT for transradial coronary angiography. However, the procedures will be performed by cardiology fellows during the 3rd year of their specialization program in cardiology.

**Investigated devices:** Ultra Curve catheter, Trapease Curve catheter, Judkins right and left. All investigated catheters are allowed for use in Poland and have CE markings.

**Type of the study**: prospective, single-blinded, randomised, controlled trial.

**Patient population:** One-hundred patients.

**The planned beginning of the study:** February 2021

**The planned end of the study**: February 2023

## Methodology:

This is a prospective, single-blinded, randomized, controlled trial enrolling patients with a diagnosis of stable coronary artery disease with qualification for invasive diagnostic coronary angiography. Before the procedure, each patient will be provided with ECG testing and will undergo blood testing in order to establish the level of basic biochemical parameters, namely blood count, INR, APTT, creatinine, eGFR, TSH and glucose.

Patients will be assigned to 1 of 3 groups by simple randomization, rolling a standard 6-sided dice (group 1: 1 and 2 points, group 2: 3 and 4, and group 3: 5 and 6).

Group 1: single-catheter technique, catheter: Trapease Curve 6F.

Group 2: single-catheter technique, catheter: Ultra Curve 6F.

Group 3: dual-catheter technique, catheters: Judkins left and right 6F.

After coronary angiography, patients will be treated in line with the current cardiological guidelines.

**Inclusion criteria:**

1) diagnosis of stable coronary artery disease with qualification for invasive diagnostic coronary angiography;
2) age above 18;
3) good pulse found on the radial artery, verified in physical examination.

**Exclusion criteria:**

1) diagnosis of acute coronary syndrome;

2) previous coronary artery bypass grafting;

3) active hemodialysis fistula in the forearm ;

4) pregnancy;

5) hyperthyroidism.

**Study endpoints:**

Investigated study endpoints include:

1) Primary endpoints:

a. catheter ostial stability rated on a 3-point scale and proper ostial artery engagement, which will be assessed by the operator performing the angiography;

2) Secondary endpoints:

a. the duration of each procedure step, including fluoroscopy time:

i. T1: time needed to introduce the diagnostic catheter, from entering the vascular sheath to reaching the ascending aorta;

ii. T2: time needed to properly engage the ostium of the RCA by the catheter positioned in the ascending aorta;

iii. T3: time of fluoroscopy during the RCA angiography recording;

iv. T4: time needed to properly engage the ostium of the LCA by the catheter positioned in the ascending aorta; in the dual-technique group, this procedure step comprised of changing the Judkins catheter from the right to left and time needed to properly engage the ostium of the LCA;

v. T5: time of fluoroscopy during the LCA angiography recording;

vi. T6: total procedural time;

b. contrast volume;

c. radiation dose;

d. incidence of complications:

Each complication will be reported in the patient's case report form. Incidents connected with catheter fracture or malfunction will be registered and reported to the producer.

**Data supervision:**

1) Data storage:

Each patient enrolled in the study will be provided with their own case report form (CRF), which will store details regarding basic medical characteristics, ongoing treatment, and results according to medical records. According to the law, the organiser of the study will be obliged to store all medical data in an available and completely safe place.

2) Data analysis:

The organizer of the study is responsible for storing the study results which will be collected via CRF forms of enrolled patients. Consequently, data will be used to create a database, which will be later analyzed in line with the study assumptions.

**Ethical concerns:**

The study will conducted in accordance with the Declaration of Helsinki (as revised in 2013) as well as ICH-GCP and local law. The study was approved by the Institutional Review Board of the Jagiellonian University (approval No.: 1072.6120.101.2019 issued on 24 April 2019) and informed consent will be collected from all the patients.

**Worksheet TRACT 2**

Group I: ULTRA 4.5 / 3.5 / 4.0

Group II: TRAP 4.5 / 3.5 / 4.0

Group III: Standard 6F JL3.5 and JR4.0

Date: …/…../……. CENTER …….

Patients' initials …… Sex: female • male •

Weight (kg) …… Height (cm) …….

Group number ……..

Investigated catheters …….

Operator's initials … - …

**Procedure details:**

Radial access: right • left •

The vessel intended to be first cannulated: RCA • LCA •

Actual order: first RCA • first LCA •

Time needed to introduce the diagnostic catheter, from entering the vascular sheath to reaching the ascending aorta **T 1 …... s**

Time needed to properly engage the ostium of the first vessel by the catheter positioned in the ascending aorta **T 2 …… s**

**Ostial stability:**

optimal …….. ☐

suboptimal …….. ☐

ineffective …….. ☐

- type of the ineffective catheter ……

Necessity to change the catheter: yes • no •

used catheter …….

Time of fluoroscopy during recording the angiography of the first vessel **T3 …….s**

Contrast volume (ml) **…….ml**

Radiation dose **…….mGy**

Time needed to properly engage the ostium of the second vessel by the catheter positioned in the ascending aorta **T4 …… s**

** for group 3:

Time needed to change the Judkins catheter **T4A ……. s**

Time needed to properly engage the ostium of the second vessel **T4B ……. s**

**Ostial stability:**

optimal …….. ☐

suboptimal …….. ☐

ineffective …….. ☐

- type of the ineffective catheter ……

Necessity to change the catheter: yes • no •

used catheter …….

Time of fluoroscopy during recording the angiography of the second vessel **T5 ……. s**

Contrast volume: **…… ml**

Radiation dose: **…… mGy**

Total contrast volume: ……. **ml**

Total radiation dose: …….. **mGy**

Total procedural time: **T6 (min/s) …/…….**

**Echocardiographic details: EF……% Asc ao …… mm LVIDd ……. mm**

**Periprocedural complications:**

Radial artery spasm: yes • no •

Pain during catheter insertion: yes • no •

Puncture-site hematoma: yes • no •

Upper limb hematoma: yes • no •

Coronary artery dissection: yes • no •

Other complications: yes • no •

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**Major adverse events:**

Myocardial infarction: yes • no •

Death: yes • no •

Necessity for another coronary angiography: yes • no •

Catheter fracture or malfunction: yes • no •

**Following treatment**:

Conservative treatment •

PCI •

IVUS •

FFR •

CABG •

Notes

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