Oral Nicorandil for Prevention of No Reflow Phenomenon in Anterior STEMI Patients undergoing Primary PCI

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Clinical Trial Number: the registration is ongoing in clinical trials.

GOV once finished the number will be provided.

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Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for parents or guardians of patients who are invited to participate in the research

Research title: **Oral nicorandil for prevention of No reflow phenomenon in Anterior STEMI patients undergoing PPCI**

Introduction and aim of the work:

Acute myocardial infarction presenting with sustained ST-segment elevation is thought to be the result of the sudden and complete obstruction of a coronary artery by the formation of a thrombus at the site of a fissured or ruptured atherosclerotic plaque ***(Zijlstra et al., 2020).***

In particular, ST-elevation myocardial infarction (STEMI) mortality remains high and continues to demonstrate significant geographical variation. Despite a relative decrease in the proportion of myocardial infarction (MI) due to STEMI over the years, it still accounts for 40% of all presentations with acute myocardial infarction (AMI) ***(Tern et al., 2021).***

Investigate the potential role of oral nicorandil in preventing the No reflow phenomenon in anterior ST-segment elevation myocardial infarction (STEMI) patients undergoing percutaneous coronary intervention (PPCI).

Assess whether nicorandil, a potassium channel activator, can effectively enhance myocardial perfusion in this specific clinical context.

Place of work:

Cardiology department at Ain Shams University hospitals and Mirs University for Science and Technology (MUST) hospital.

Number and Selection of participants:

- Using PASS 15 program for sample size calculation, setting power at 80% and alpha error at 0.05 and according to "Qian et al, 2022", the expected incidence of no-reflow phenomenon in nicorandil group = 9.2% and in control group = 26.3% Sample size of 150 patients per group will be needed to detect the difference between two groups.

Plan of the work:

After your consent achievement and fully explained about the steps of research, the subjects of both groups will be subjected to the following:

● All the included patients will be subjected to:

- ***Full history taking;*** focusing on risk factors for coronary artery disease (CAD):
  1. Age
  2. Sex
  3. Risk factors:
     - ✓ Diabetes mellitus (DM)
     - ✓ Hypertension (HTN)
     - ✓ Family history of ischemic heart disease (IHD)
     - ✓ Dyslipidemia
     - ✓ Chronic kidney disease (CKD)
     - ✓ Smoking status

4. Clinical presentation: Killip classification will be applied for clinical assessment of the included patients. Killip classes will be defined as given below:
   - ✓ Killip class I: patients without any clinical sign of heart failure (HF)
   - ✓ Killip class II: patients with crackles or rales in the lungs, elevated jugular venous pressure, and an S3 gallop
   - ✓ Killip class III: patients with evident acute pulmonary edema
   - ✓ Killip class IV: patients with cardiogenic shock or hypotension (systolic blood pressure < 90 mmHg) and features of low cardiac output (oliguria, cyanosis, or impaired mental status)
5. Vital data

- ***Electrocardiogram:*** The standard 12-lead electrocardiogram will be recorded on admission, immediately after PCI and subsequently at 2, 4 h after PCI.

- ***Laboratory investigations including:***
  - ✓ Creatinine serum level on admission

- ***Study Intervention:*** Patients will be randomized to the treatment group the patients will be split into two equal groups: Nicorandil 20 mg single oral dose will be given to group A, the study group, and group B, the control group, won't receive nicorandil.

- ***Primary PCI*** will be performed by an expert interventional cardiologist who performs more than 100 primary PCI per year ***(Ibanez et al., 2017)***.

- ***Angiographic data including****:*
  1. Final TIMI flow grade will be assessed by at least 2 experienced interventional cardiologists blinded to the administered drug. The effect of oral nicorandil will be documented by improvement in TIMI flow grade.
  2. CAD severity with Number of diseased vessels affected and Syntax I score

- ***Echocardiographic assessment:*** Transthoracic echocardiography will be performed after PCI. Left ventricular ejection fraction (LVEF) will be

measured by an independent observer blinded to the treatment allocation. Echocardiography including the left ventricular function will be measured by the modified Simpson's method on discharge.

- The history taking and examinations will be carried out in a private setting to protect the patient's privacy and guarantee the confidentiality of the data collected.

Benefits expected from the study:

Investigate the potential role of oral nicorandil in preventing the No reflow phenomenon in anterior ST-segment elevation myocardial infarction (STEMI) patients undergoing percutaneous coronary intervention (PPCI).

Assess whether nicorandil, a potassium channel activator, can effectively enhance myocardial perfusion in this specific clinical context.

Conducting the consent:

The consent will be conducted to the legal guardian or the patient by the investigator, Doctor **Norhan Gamal Gharieb Ibrahim** in the **Cardiology** Department, Ain Shams University Hospital. Literate individuals will be left to read the consent followed by its explanation by the mentioned investigator, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

Hypotension with signs of organ hypoperfusion: oliguria or elevated serum lactate.

Reimbursements in cases of risks and complications:

Should your patient get physically injured as a result of research-related procedures, Doctor **Norhan Gamal Gharieb Ibrahim** will provide first-aid medical treatment.

Alternatives to participating:

In case of refusing to participate in this research, your patient will be followed up and will receive his treatment as planned.

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the

research is complete, you will be informed regarding your patient `s research results and also further information regarding your patient `s health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at anytime. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient's participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

Contact Information:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the investigator, **Norhan Gamal Gharieb Ibrahim** at mobile number: 01155207727. You can also call the assistant supervisor **Dr. Ahmed Mostafa Ahmed Muhammed** at mobile number: 01009757069. If you have any problems or concerns about the study, you can also call **Prof. Islam Mahmoud Bastawy** the main supervisor at mobile phone number: 01288700196

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I

have the right to withdraw from the research at any time without in any way affecting my patient`s medical care.

- Name of participant:
- Signature of legal guardian:
- Or participant:
- Identity number or finger print: …….
- Date:

I have accurately read or witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher: **Norhan Gamal Gharieb Ibrahim**
- Signature of researcher:
- Date:

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is a committee whose task is to make sure that research participants are protected from harm.

If you wish to find more about Ethical Committee of Scientific research. Contact:
Name:
Address:
Telephone number: