Tour de Borobudur Troponin Study on Predictors and Synergistic Role of MDA and Hs-CRP Levels (TdBTS)

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ClinicalTrials.gov Identifier: NCT03310450

Study Protocol

12th October 2017

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General Procedure

1. Study was conducted only with observation without any intervention.
2. Data collection was done a day before cycling activity and immediate after cycling activity.
3. Participants of 2017 Indonesia Tour de Borobudur (TdB) and North Coast (NC) who volunteer to participate in the study prior to cycling activity will be requested to complete data by filling out forms, conducted interviews, conducted doctor examination, measurement of weight, height, waist circumference, hips, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), ECG examination and blood sampling.
4. Immediately after cycling (at the finish), weight measurements, interviews, ECG examination, copying workout from Polar® heart rate monitor (HRM) and second blood sampling was done in the same manner.
5. If the participant stops the cycling activity before the finish line, the post-race data was taken at the stop point as soon as possible.

Interviews

1. The interview was conducted by the research team officer to the TdB participants who became respondents.
2. Interview was conducted pre- and post-cycling activities.
3. Pre-cycling interviews was done to collect some data, i.e. identity and demographic data, training characteristics, medical history and family history with coronary artery diseases, personality and sleep quality.
4. Immediate post-cycling interview was conducted to collect some data, i.e. the perceptions of the level of energy expenditure during cycling (rate of perceived exertion=RPE), subjective complaints and the type and amount of drink be taken.

Anthropometry Measurement

1. Anthropometry measurements were taken a day before the cycling activity, specifically the weight measurement done just before the start.
2. Participants wore comfortable clothes.

Physical Examination by Doctor

1. The physical examination, SBP, DBP was done together with the measurement of anthropometry.
2. Doctor's examination also states the participant was eligible or not to participate in cycling activities as a study participant.

ECG

1. ECG examination was done twice on the day before the cycling and immediately after completion of cycling activity (at the finish line).
2. ECG examination was done by attaching leads at certain points on the chest and as well in wrists and ankles).
3. To ensure the attachment is appropriate for both checks (pre- and post-race), the study participants will be marked with water-resist ink.

Blood sampling

1. Blood sampling was done twice; the day before cycling and immediately after completion of cycling activity (at the finish line).
2. Blood sampling was performed for measuring Hb level, total cholesterol, HDL, hs-cTnI, hs-CRP and MDA levels.
3. Blood sample then was examined in Biotechnology Laboratory (GAKI) FK UNDIP and Clinical Laboratory of Cito (group) Semarang

Copying workout from Polar® heart rate monitor

1. For participants that using Polar HRM, data retrieval was done by copying from the gadget.
2. Doctor's examination also states the participant was eligible or not to participate in cycling activities as a study participant.

Cycling activity

1. Cycling activities follow the regulations set by the TdB or NC committee, which includes routes, obey the rules of traffic and other technical guidelines.
2. Study participants conducted cycling activities at speeds according to their own ability and pace.
3. Study participants were allowed to take a rest anytime and any length but should be recorded from the Polar HRM, by pressing the "PAUSE" button.
4. Study participants were allowed to drink and eat as they wish but must record (remember) the amount and type of food/beverage consumed.
5. Study participants who were unable to complete the race, when stopping their activity supposed to contact the research team whose phone number has been given, for the post-race data collection and evacuation.

Ethical clearance approval

The study protocol was approved by the Ethical Committee of the Faculty of Medicine, University of Diponegoro/ Dr. Kariadi General Hospital, Semarang, Indonesia; and informed consent was obtained from all participants.