Appendix 1

Microvascular and metabolic effects of high-intensity interval training and intermittent fasting in overweight or obese, sedentary women with cardiometabolic risk factors: HIIT-FAST, a randomized clinical trial

**WHO Trial Registration Data Set**

Primary Registry and Trial Identifying Number

clinicaltrials.gov

NCT03236285

Date of Registration in Primary Registry

07/31/2017

Secondary Identifying Numbers

N/A

Source(s) of Monetary or Material Support

National Institute of Cardiology and Fundação de Amparo à Pesquisa do Rio de Janeiro (FAPERJ 203.381/2015).

Primary Sponsor

National Institute of Cardiology
Secondary Sponsor(s)
N/A

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Public Title
Effects of high-intensity exercise and intermittent fasting in overweight or obese, sedentary women at risk for cardiac disease

Scientific Title
Microvascular and metabolic effects of high-intensity interval training and intermittent fasting in overweight or obese, sedentary women with cardiometabolic risk factors: HIIT-FAST, a randomized clinical trial
Countries of Recruitment
Brazil

Health Condition(s) or Problem(s) Studied
Obesity; metabolic syndrome

Intervention(s)
High-intensity interval training; continuous exercise; intermitente fasting

Key Inclusion and Exclusion Criteria
Inclusion: Age; gender; obesity or overweight; premenopausal status

Exclusion: Known cardiovascular, pulmonar or other systemic disease; inability to exercise

Study Type
Interventional, randomized study, with 4 arms. Masking only for data analysis.
Purpose: to assess the effects of 2 exercise programs, combined or not with fasting, on overweight or obese women.
Study to be initiated.

Date of First Enrollment
October 2017

Target Sample Size
80
Recruitment Status
Pending: participants are not yet being recruited or enrolled at any site

Primary Outcome
Capillary density measured by intravital microscopy

Key Secondary Outcomes
Microvascular reactivity measured by laser speckle contrast imaging
Serum glucose, lipids measured by biochemical analyses
Exercise capacity measured by exercise treadmill test
Weight, body mass index