Correlation between postprandial very-lowdensity lipoprotein and atrial remodeling

Submission date 08/06/2020	Recruitment status No longer recruiting	[] Prospectively registered[X] Protocol
Registration date 09/06/2020	Overall study status Completed	 [_] Statistical analysis plan [X] Results
Last Edited 24/09/2020	Condition category Circulatory System	Individual participant data

Plain English summary of protocol

Background and study aims

Metabolic syndrome is the medical term for a combination of diabetes, high blood pressure and obesity. This study aims to determine the role of molecules called lipoproteins in atrial myopathy (heart disease) in metabolic syndrome, and to identify the toxic lipoprotein as a new target for the prevention of atrial fibrillation (irregular heart rate).

Who can participate? Healthy volunteers and patients with metabolic syndrome

What does the study involve?

Participants will be randomly allocated into two groups. Both groups have their ordinary medications continued, while participants in the intervention group will receive team-guided lifestyle modification guided by a specific health care team, including weight control, tailored physical activity, screening and treatment for sleep apnea, smoking cessation and alcohol abstinence. All participants will be followed up for 12 months to collect data including demographics, body mass index, blood pressure, echocardiography, electrocardiography (heart examinations), and blood sample collection.

What are the possible benefits and risks of participating? The participants may benefit from receiving their heart examination results. There is a risk of bruising from the blood sample, but mostly mild and self-limited.

Where is the study run from? Kaohsiung Medical University Hospital (Taiwan)

When is the study starting and how long is it expected to run for? January 2018 to December 2021

Who is funding the study? National Health Research Institutes (Taiwan) Who is the main contact? Prof. Hsiang-Chun Lee hclee@kmu.edu.tw

Contact information

Type(s) Scientific

Contact name Prof Hsiang-Chun Lee

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers Nil known

Study information

Scientific Title The alliance of lipoproteins-lipids with early atrial myopathy and atrial fibrillation

Study objectives

The negative-charged very-low-density lipoprotein (VLDL)-induced structural and electrical remodelling is an important pathogenesis of early atrial myopathy for atrial fibrillation (AF) vulnerability in metabolic syndrome (MetS).

Ethics approval required Old ethics approval format

Ethics approval(s)

Approved 12/06/2017, Institutional Review Board-I, Kaohsiung Medical University Hospital (100 Tzyou 1st Rd, Kaohsiung, Taiwan; +886 (0)7 31211-1 ext. 6646; irb@kmuh.org.tw), ref: KMUHIRB-E(I)-20170256

Study design Observational longitudinal study

Primary study design Observational

Secondary study design Longitudinal study

Study setting(s) Hospital

Study type(s) Prevention

Participant information sheet

Not available in web format, please use contact details to request a particular information sheet

Health condition(s) or problem(s) studied

Prevention of atrial fibrillation in patients with metabolic syndrome

Interventions

Participants will be randomized into two groups. Both groups have their ordinary medications continued, while participants in the intervention group will be intervened with a life modification guided by a specific health care team. The team-guided lifestyle modification includes weight control, tailored physical activity, screening and treatment for sleep apnea, smoking cessation and alcohol abstinence. All participants will be followed up for 12 months.

Intervention Type

Behavioural

Primary outcome measure Atrial size measured using ultrasonography at baseline, 6, 18, 24, and 36 months

Secondary outcome measures

Lipid profiles measured using Ultra Performance Liquid Chromatography (UPLC) at baseline, 6, 18, 24, and 36 months

Overall study start date 01/01/2018

Completion date 31/12/2021

Eligibility

Key inclusion criteria

Age 20 to 80 years
 Healthy volunteers or patients diagnosed with metabolic syndrome

Participant type(s) Mixed

Age group Adult

Sex Both

Target number of participants 80 healthy volunteers and 80 metabolic syndrome patients

Total final enrolment 167

Key exclusion criteria Serious infection

Date of first enrolment 23/01/2018

Date of final enrolment 05/10/2018

Locations

Countries of recruitment Taiwan

Study participating centre Kaohsiung Medical University Hospital 100 Tzyou 1st Road Kaohsiung Taiwan 807

Sponsor information

Sponsor details

100 Tzyou 1st Rd Kaohsiung City Taiwan 807 +886 (0)7 3121101 hclee@kmu.edu.tw

Sponsor type Hospital/treatment centre

Website http://www.kmuh.org.tw/

ROR https://ror.org/02xmkec90

Funder(s)

Funder type Government

Funder Name National Health Research Institutes, Taiwan

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-review journal.

Intention to publish date 06/12/2020

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>	results		03/07/2020	No	No
Results article		22/09/2020	24/09/2020	Yes	No