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Correlation between postprandial very-low-density lipoprotein and atrial remodeling

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

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
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Contact information

Type(s)
Scientific

Contact name
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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
1. Age 20 to 80 years
2. 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

Organisation
Kaohsiung Medical University Chung-Ho Memorial Hospital

Sponsor details
100 Tzyou 1st Rd
Kaohsiung City
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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?
Protocol file			03/07/2020	No	No
Results article	results	22/09/2020	24/09/2020	Yes	No