

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

Submission date 08/06/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/09/2020	Condition category Circulatory System	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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(l)-20170256

Study design

Observational longitudinal study

Primary study design

Observational

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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Sponsor information**Organisation**

Kaohsiung Medical University Chung-Ho Memorial Hospital

ROR

<https://ror.org/02xmkec90>

Funder(s)**Funder type**

Government

Funder Name

Results and Publications

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?
Results article	results	22/09/2020	24/09/2020	Yes	No
Protocol file			03/07/2020	No	No