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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
Prof Hsiang-Chun Lee

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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(I)-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
807

# Sponsor information

**Organisation**
Kaohsiung Medical University Chung-Ho Memorial Hospital

**ROR**
https://ror.org/02xmkec90

# Funder(s)

**Funder type**
Government

**Funder Name**

National Health Research Institutes, Taiwan

# 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | | 03/07/2020 | No | No |