Jul 23, 2021

ANGPTL-protocil-YCU

Ty[1]

[1]Department of Endocrinology and Diabetes, Yokohama City University Medical Center

dx.doi.org/10.17504/protocols.io.bmjsk4ne

onyogora

DOI

dx.doi.org/10.17504/protocols.io.bmjsk4ne

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0255147

DOCUMENT CITATION

Ty 2021. ANGPTL-protocil-YCU. **protocols.io** https://dx.doi.org/10.17504/protocols.io.bmjsk4ne

MANUSCRIPT CITATION please remember to cite the following publication along with this document

Harada M, Yamakawa T, Kashiwagi R, Ohira A, Sugiyama M, Sugiura Y, Kondo Y, Terauchi Y (2021) Association between ANGPTL3, 4, and 8 and lipid and glucose metabolism markers in patients with diabetes. PLoS ONE 16(7): e0255147. doi: 10.1371/journal.pone.0255147

CREATED

Sep 21, 2020

LAST MODIFIED

Jul 23, 2021

DOCUMENT INTEGER ID

42322

PROTOCOL

1. Purpose

1) To investigate the relationship between angiopoietin-like proteins (ANGPTLs) and pathological conditions such as obesity, insulin resistance, and dyslipidemia in diabetes
2) To investigate how circulating ANGPTLs levels are altered by improved lipid and glycemic control

Endpoints:

lPrimary endpoints:
Relationship between diabetes-related index (glycated hemoglobin [HbA1c] level and insulin resistance) and ANGPTL levels
lSecondary endpoints:
1)Atherosclerosis (macrovascular disease, minimal vascular disease, and carotid echo)
2) Obesity (body mass index [BMI] and visceral fat area)
3) Lipid markers (Apo proteins, fatty acid fraction, lipoprotein lipase [LPL])
4) Changes in ANGPTL levels due to improved glycemic and lipid control

2. Inclusion Criteria

In-patients who met all of the following criteria:
1)Diabetes patients aged 20 years or older at the time of registration
2) Patients taking lipid-related drugs or having dyslipidemia
3) Patients undergoing hypoglycemic treatment only with dietary, exercise, or insulin therapy or oral hypoglycemic drugs
4) Patients who provided written informed consent to participate in this study

3. Exclusion Criteria

1) Patients with severe diabetic ketoacidosis
2) Patients with diabetic coma or precoma
3) Patients with severe infections
4) Patients with severe trauma
5) Other patients considered by the attending physician to be inappropriate for the study

4. Sample Size and Enrollment Period

Planned sample size: 100 patients with type 2 diabetes
Enrollment period: September 2017 (after ethics committee approval) – December 31, 2020

5. Study Design

Prospective observational study

6. Study Participation and Patient Registration/Allocation Procedures

Written consent was obtained from patients who satisfied all criteria. Patients who gave consent were enrolled in the study. An identification code was assigned to each registered patient for linkable anonymization. A table was created for the chart number of each patient, which was assigned another number. Thus, patient information was managed in a format that does not allow patient identification. Informed consent forms are stored strictly in a locker.

7. Observations, Examinations, and Reported Items

Patient characteristics: The following items were investigated at the time of enrollment:
Sex, age, height, body weight, smoking/drinking history, medical history, diabetes history, diabetic complications, diabetes medications, and other medications for lifestyle-related diseases
Laboratory tests: Blood sampling was performed twice per day, after admission and before discharge.
lFasting biochemical tests: TC, TG, HDL-C, LDL-C, non-HDL-C, AST, ALT, γGTP, BUN, uric acid, serum creatinine, Na, Cl, K, HbA1c, fasting blood glucose, glyco-albumin, fasting C-peptide, urinary albumin, urinary protein, urinary glucose, free fatty acid fractions,lipoprotein lipase, and apoproteins (these are the tests that are performed in routine medical care)
lANGPTL2, ANGPTL3, ANGPTL4, ANGPTL8, and cytokines, such as adiponectin and TNF-α (these factors were inspected for the purpose of this research)
Image inspection: ABI/PWV, IMT measurement, and visceral fat CT

8. Analysis

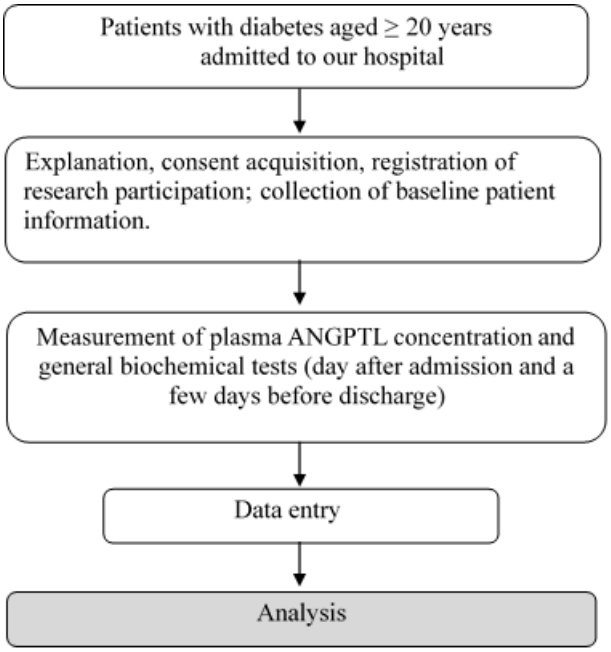
Data analysis was performed by the Department of Biostatistics at Yokohama City University Medical School under the supervision of a statistician.

9. Status of Funding Sources for Research and Conflicts of Interest Related to the Researchers

This study was conducted using basic research funds and scholarship donations paid by the companies Daiichi Sankyo Co., Ltd., Sanofi Co., Ltd., and Ono Pharmaceutical Co., Ltd., to the Department of Endocrinology and Diabetes, Yokohama City University Medical Center. This study was conducted from a medical point of view and does not benefit any particular company or organization.

Analysis

Citation: Ty (07/23/2021). ANGPTL-protocil-YCU. https://dx.doi.org/10.17504/protocols.io.bmjsk4ne



Citation: Ty (07/23/2021). ANGPTL-protocil-YCU. https://dx.doi.org/10.17504/protocols.io.bmjsk4ne