Statistical Analysis Plan

Title: Value of Glycated Albumin in Intervention of Glycemic Control in Patients with Type 2 Diabetes: A Multicenter, Randomized Controlled Clinical Study

NCT No.: NCT05227677

VERSION： 1.0

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Abbreviation

Abbreviation	Definition
AE	Adverse events
CRF	Case report form
FAS	Full Analysis Set
GA	Glycated Albumin
GCP	Good Clinical Practice for Drug Clinical Trials
HbA1c	Hemoglobin A1c
PPS	Per Protocol Set
SAE	Severe adverse events
SS	Safety set

1. Introduction

This Statistical Analysis Plan (SAP) has been prepared for the clinical trial titled:

"A Multicenter, Randomized Controlled Clinical Trial to Evaluate the Interventional Value of Glycated Albumin (GA) in Glycemic Control for Patients with Type 2 Diabetes Mellitus"

sponsored by Asahi Kasei Pharma Corporation. This document provides a detailed description of the statistical analysis methods and procedures to be applied in the study.

The SAP is based on the Protocol Version 3.0 dated March 8, 2023, and the Case Report Form (CRF) Version 3.0 dated February 1, 2024.

2. Research Objective

The objective of this study is to verify the hypothesis that:

"Adjusting treatment regimens based on GA test results is more effective in helping patients achieve target average blood glucose levels (HbA1c)."

3. Research Design

3.1.Research groups

Subjects will be randomly assigned to two groups:
- Intervention Group (Group A)
- Control Group (Group B)

Each group will consist of 100 subjects. Randomization will be performed using block randomization generated by SAS version 9.4 or later, ensuring reproducibility. Randomization letters will be used to assign eligible subjects in a 1:1 ratio to either Group A or Group B.

All subjects will receive antidiabetic treatment according to standard clinical practice. The use of sulfonylureas, glinides, insulin, or insulin analogs is prohibited in this study.

At the first follow-up visit (Month 1), GA will be measured for subjects in the intervention group. Based on the GA normalization principle, the investigator will adjust the treatment regimen accordingly. At Month 2 and Month 3, blood samples will be collected, and GA will be measured after the follow-up period,

but these results will not be used to adjust treatment and will be used only for statistical analysis.

Subjects in the control group will also have blood samples collected at Month 1, Month 2, and Month 3, with GA measured after the follow-up period for statistical analysis only.

3.2 Study Procedures and Follow-up Schedule

The research steps and follow-up plan are shown in Figure 1 and Table 1.

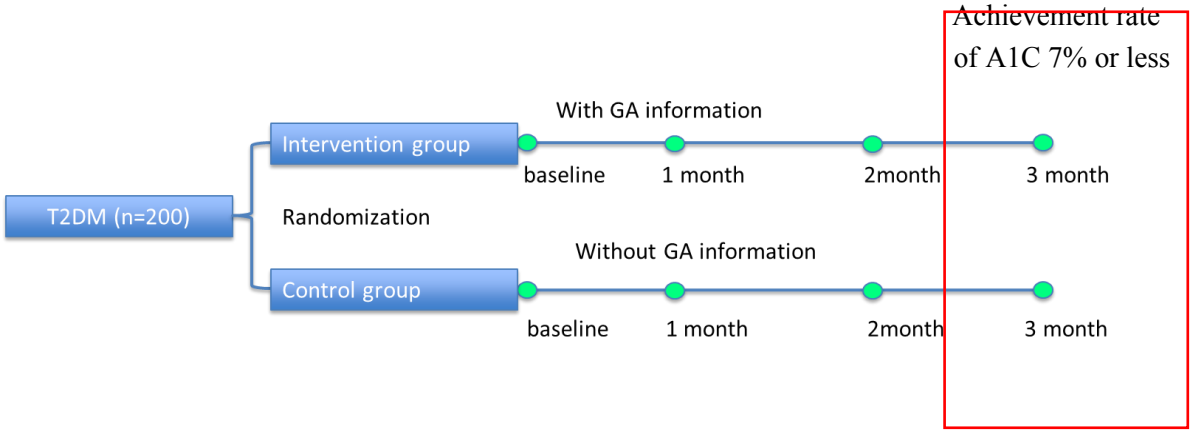

Figure 1. Research process diagram

Table 1 Research flowchart

	Screening visits	Baseline[#]	Follow-up				Measurement of GA Frozen sample
Visit number	1	2	3A	3B	4	5	
visit time	Days -7 to 0	Day 0	4 weeks (baseline: 28 ± 3 days)	4 weeks (follow-up visit 3A + 5 days) [*]	8 weeks (baseline 56 ± 3 days)	12 weeks (baseline 84 ± 3 days)	Follow-up visit completed
informed consent	X						
Demographic information (name,	X						

gender, ethnicity, date of birth)							
Medical history [a]	X						
Physical examination [b]	X		X[h]	X[g]	X	X	
Collect samples and perform the following laboratory tests：							
Blood glucose-related tests [c]	X[i]					X	
Complete blood count [d]	X[i]					X	
Liver and kidney function [e]	X[i]					X	
lipids [f]	X[i]					X	
Blood or urine pregnancy test	X[i]						
Blood sample collection (for GA measurement)	X		X[h]		X		
Inclusion/exclusion criteria	X	X					
Confirm eligibility for enrollment		X					
Randomization		X					
Treatment plan		X					
Distribution of subject diaries		X	X[h]	X[g]	X		
Check and collect participants' report			X[h]	X[g]	X	X	
GA measurement			X[g]			X	
Adjust treatment plan			X[h]	X[g]	X		
Recording medication treatment	X	X	X[h]	X[g]	X	X	
Record and review		X	X[h]	X[g]	X	X	

(since the previous visit) (S) AE							
study termination						X	
Determination of GA in frozen samples							X

Notes:
#If screening and baseline are conducted on the same day, all duplicate steps need only be performed once
*It is best to conduct the visit within 3 days after the 3A visit, with a maximum of 5 days
a. Medical history includes information such as disease course and treatment methods
b. Physical examination includes: height, weight, waist circumference, blood pressure, pulse (screening period); weight, waist circumference, blood pressure, pulse (follow-up period)
c. Blood glucose-related tests include: fasting blood glucose, HbA1c, fasting C-peptide, fasting insulin
d. Complete blood count: red blood cells (RBC), white blood cells (WBC), platelets (PLT), hemoglobin (HGB)
e. Liver and kidney function: total bilirubin (Tbil), alanine transaminase (ALT), aspartate transaminase (AST), total protein (TP), albumin, blood urea nitrogen (BUN) or urea (Urea), serum creatinine (Cr), uric acid (UA)
f. Lipid profile: Total cholesterol (TC), triglycerides (TG), low-density lipoprotein (LDL-C), high-density lipoprotein (HDL-C)
g. Only for Group A participants
h. Only for Group B participants
i. If the patient has laboratory test results within the past 7 days, historical results may be used, and repeat testing is not required.

3.3. Sample size

Each group (Intervention and Control) will include 100 subjects.
The sample size was determined based on a preliminary single-center pilot study (n=40), which showed that the proportion of subjects achieving HbA1c < 7% after 3 months was 76.9% in the intervention group and 46.2% in the control group ($p = 0.226$).
Assuming:

- $\alpha = 0.05$ (two-sided significance level)
- Power = 0.8
- Effect size = 30% difference between groups

Considering factors such as:

- Follow-up completion rate in the pilot study (72.5%)
- Multicenter design

The target sample size was calculated to be 100 subjects per group.

3.4. Expected Overall Duration of the Clinical Trial

Considering the time required for clinical trial institutions to complete patient enrollment, follow-up, and sample testing, the study is expected to take 18 months from the first patient enrollment to database lock. If the implementation time exceeds the expected duration, the protocol will not be modified.

4. Study Endpoints

4.1. Efficacy Endpoints

4.1.1. Primary Endpoints

Proportion of subjects achieving HbA1c < 7% at Visit 5 (Week 12 ± 3 days)

Percentage of subjects = = (Number of subjects with HbA1c < 7%) / (Total number in efficacy analysis set) × 100%

The efficacy analysis set includes:

- Full Analysis Set (FAS)
- Per Protocol Set (PPS)

4.1.2. Secondary Endpoints

Secondary endpoints include:

-Proportion of subjects with HbA1c < 6.5% at Visit 5

-Proportion of subjects with HbA1c < 6.0% at Visit 5

-Change in HbA1c from screening to Visit 5

-Incidence and frequency of hypoglycemia

-Change in pancreatic β-cell function

-Change in insulin resistance

-Change in body weight

-Change in waist circumference

-Change in BMI

All secondary endpoints will be evaluated as changes from screening to the end of treatment (Visit 5), including absolute and percentage changes.

4.2. Safety indicators

4.2.1. Exposure time: Not applicable.

4.2.2. Adverse events (AEs)

Adverse event(AE):

Adverse medical events that occur during the clinical trial, regardless of whether they are related to this trial.

Serious Adverse Events(SAE):

Refers to events occurring during a clinical trial that result in death or a serious deterioration in health, including fatal diseases or injuries, permanent defects in

bodily structure or function, hospitalization or prolonged hospitalization, medical or surgical intervention to prevent permanent defects in bodily structure or function, fetal distress, fetal death, or congenital abnormalities, or congenital defects.

Note: The following situations are not considered SAEs:
-Hospitalization that was planned prior to screening and did not result in a serious deterioration in health;
-Expected, non-worsening fluctuations in pre-existing or detected abnormal conditions or diseases at the time of screening;
-Hospitalization or prolonged hospitalization during the clinical trial period as specified in the protocol (if applicable).

4.2.3. Device defects: Not applicable.

4.2.4. Laboratory tests

Collected in the CRF:
-**Glucose-related tests**: results of fasting blood glucose, glycated hemoglobin (HbA1c), fasting C-peptide, fasting insulin, and clinical assessment;
-**Complete blood count**: results of red blood cells (RBC), white blood cells (WBC), platelets (PLT), hemoglobin (HGB), and clinical assessment;
-**Liver and kidney function**: Total bilirubin (Tbil), alanine transaminase (ALT), aspartate transaminase (AST), total protein (TP), albumin, blood urea nitrogen (BUN) or urea (Urea), serum creatinine (Cr), uric acid (UA), estimated glomerular filtration rate (eGFR) test results and clinical assessment;
-**Lipid profile**: Total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C) test results and clinical assessment;

4.2.5. Electrocardiogram (ECG): Not applicable.

4.2.6. Other Assessments:
-Physical examinations: The CRF collects the following results from participants: height, weight, waist circumference, blood pressure, and pulse rate (during the screening period); weight, waist circumference, blood pressure, and pulse rate (during the follow-up period).
-GA measurement: The CRF collects the results of GA measurement tests and their clinical assessment (normal, abnormal without clinical significance, abnormal with clinical significance, not tested).
-Pregnancy test: The CRF collects whether the subject underwent a pregnancy test, the test date, and the result (negative or positive).

4.3. Demographic data and disease characteristics

-**Demographic data**: The CRF collects the subject's date of birth, age, gender, and

ethnicity.

-**Diabetes diagnosis history**: The CRF collects information on whether the subject is a newly diagnosed type 2 diabetes patient, the date of the first type 2 diabetes diagnosis, whether antidiabetic medications were used in the past three months, the medication name, start date, whether use was continuous, and the end date.

-**History of hypoglycemic episodes**: The CRF collects information on whether the subject had a history of hypoglycemic episodes within the year prior to the screening date, the start date, the end date, and whether the episodes were severe.

-**Past medical history**: The CRF collects information on whether the subject has a history of relevant medical conditions, the disease name, the start date, whether the condition is ongoing, the end date, and the treatment method.

4.4. Concomitant Medications

The CRF collects information on whether the subject has any concomitant medications during the study period, including the drug name, start date, end date, whether it is ongoing, single dose, dose unit, administration frequency, route of administration, indication, and associated disease name.4.5. Protocol Deviations and Medication Adherence

4.5. Protocol Deviation and Medication Adherence

Protocol Deviation: Clinical trials must adhere to GCP principles and comply with the trial protocol approved by the Ethics Committee. Any intentional or unintentional deviation from or violation of GCP principles and the trial protocol is referred to as protocol deviation or protocol violation.

Medication Adherence: The CRF collects information on the participant's medication adherence since the last visit, including whether antidiabetic medications were taken as scheduled (never missed, rarely missed [no more than 3 times per week], frequently missed [3 or more times per week], almost never taken, or taken in excess), whether antidiabetic medications were missed or taken in excess since the last visit, the medication name, administration details, and the total missed/overdose total dose, and unit of measurement.

5. Statistical assumptions

Not applicable.

6. Analysis data set

Randomized population: The entire population that received randomization is considered the randomized population.

Full analysis set (FAS): Participants who received randomization, met the study eligibility criteria, and had baseline measurements for the primary efficacy outcome. The FAS analysis follows the intention-to-treat (ITT) principle.

Per-protocol set (PPS): Participants in the FAS who demonstrated good compliance and had no important protocol deviations that affected the primary efficacy assessment (specific criteria will be confirmed during data verification).

Safety set (SS): All participants with at least one safety assessment are included in the safety analysis.1. Statistical Methods

7. Statistical Methods

7.1. General Statistical Considerations

All subject-related, efficacy-related, and safety-related data collected must be included in the statistical analysis. In the statistical tables, the subject number serves as the unique identifier for subjects in this study.

Statistical analysis will be performed using SAS software (version 9.4 or higher).

Baseline Definition: The last valid measurement or record taken prior to administration.

General Principles for Statistical Description: Quantitative indicators will be described by calculating the mean, standard deviation, median, minimum value, maximum value, lower quartile (Q1), and upper quartile (Q3). Categorical indicators will be described using the number of cases and percentage for each category. **General principles of statistical inference**: Statistical description and testing of data will be conducted based on the characteristics of the data, selecting appropriate descriptive measures and testing methods.

For comparisons between groups of quantitative data, paired t-tests or Wilcoxon rank-sum tests will be used; for comparisons between groups of categorical data, chi-square tests or Fisher's exact probability tests will be used; and for comparisons of ordinal data, Wilcoxon rank-sum tests will be used. All statistical tests are two-sided (unless otherwise specified), and a p-value less than 0.05 is considered statistically significant (unless otherwise specified). Unless otherwise specified, statistical descriptions and inferences based on follow-up visits include only data from scheduled visits. For baseline assessments and clinical significance evaluations, data from both scheduled and unscheduled visits should be included.

Principles for retaining decimal places: The minimum and maximum values retain the same number of decimal places as the original values. The mean and its confidence interval limits, median, Q1, and Q3 have one additional decimal place compared to the original values. The standard deviation has two additional decimal places. Percentages and their confidence interval limits retain one decimal place (but for efficacy analysis, two decimal places are retained).P-values should be retained with four decimal places. If the P-value is less than 0.0001, it should be

presented as '<0.0001'; if the P-value is greater than 0.9999, it should be presented as '>0.9999'. The decimal places of data in the checklist should be the same as those in the original data.

7.2. Data processing methods

7.2.1. Advance withdrawl and missing data

All missing data will not be imputed.

7.2.2. Derived and converted data

Islet β-cell function; $HOMA-\beta = \frac{20\times FINS}{(FPG-3.5)}$;

Insulin resistance level. $HOMA-IR = \frac{FINS\times FPG}{22.5}$

Among these, FINS represents fasting insulin (units: μU/ml), and FPG represents fasting blood glucose (units: mmol/L).

Diabetes Duration (days) = (Date of informed consent – Date of first diagnosis of type 2 diabetes) + 1.

Adherence (%) = Actual total dose taken (mg) (i.e., prescribed total dose ± total dose taken in excess/omitted) / Prescribed total dose (mg) * 100%, rounded to one decimal place.

The total dose (including all medications taken by the subject) (mg)

= $\sum_{i=3A/3B}^{5} Single\ dose\ (mg) * Dosage\ frequency * (Start\ date\ of\ next\ prescription/Actual\ date\ of\ visit\ 5 - Start\ date\ of\ current\ prescription)$

where the dosing frequency is once daily, dosing frequency = 1;
dosing frequency is twice daily, dosing frequency = 2;
dosing frequency is three times daily, dosing frequency = 3;
dosing frequency is four times daily, dosing frequency = 4;
dosing frequency is every other day, dosing frequency = 0.5;
Administration frequency is once weekly, administration frequency = 1/7, for visits 3A/3B, 4, 5.

Missed/extra total dose (including all drugs taken by the subject) (mg)

= $\sum_{i=3A/3B}^{5} Missed\ doses\ since\ last\ visit/Total\ dose\ taken,$

where is visit 3A/3B, 4, 5.

7.2.3 Special Data Notes

Subjects 01-002, 01-045, 04-005, and 09-007 were randomized despite not meeting inclusion/exclusion criteria. They will be included in both the screen failure and randomized subject counts.

Subject 01-016 was randomized in error due to premature envelope opening and will be counted as a screen failure.

7.3 Study paticipants

7.3.1 Subject Distribution

Count the number of subjects who signed informed consent. Count the number of screen failures and randomized subjects.

Among all randomized subjects, calculate the number and percentage who completed the study and who withdrew early, along with reasons for early withdrawal.

Provide summaries by study site and list of subject distribution.

7.3.2 Protocol Deviations

For all enrolled subjects, calculate the number and percentage of subjects with major protocol deviations during the study.

Provide summaries by study site and a list of all protocol deviations or violations.

7.3.3 Analysis data set

For all enrolled subjects, calculate the number and percentage included in: Full Analysis Set (FAS), Per Protocol Set (PPS), and Safety Set (SS). Summarize reasons for exclusion from each analysis set.

Provide summaries by study site and a list of subjects included in each analysis set.

7.3.4 Demographics and Baseline Characteristics

Analysis will be based on the Full Analysis Set (FAS).

Demographics: For continuous variables (e.g., age): report number of subjects, mean, standard deviation, median, Q1, Q3, minimum, and maximum.

For categorical variables (e.g., sex, ethnicity): report frequency and percentage for each category.

Provide summaries by study site and a list of demographic data.

Diabetes Diagnosis History: Count and report the number and percentage of newly diagnosed type 2 diabetes patients and those who used antidiabetic drugs in the past 3 months. Provide descriptive summary of diabetes duration.

List of newly diagnosed type 2 diabetes patients.

Hypoglycemia History:

Count and report the number and percentage of subjects with hypoglycemia episodes within 1 year prior to screening.

List of subjects with hypoglycemia history.

Medical History: Count and report the number and percentage of subjects with relevant medical history.

Use MedDRA/C [v27.0] coding, summarized by SOC/PT. Present SOC and PT in descending order of total percentage.

List of subjects with medical history.

7.3.5 Concomitant Medications:

Analysis will be based on the Full Analysis Set (FAS).

Concomitant medications will be coded using WHODrug GLOBAL (B3) C [V2024MAR].
Medications will be summarized by ATC classification.
A list of subjects and their concomitant medication usage will be provided.

7.3.6 Treatment Compliance

Analysis will be based on the Full Analysis Set (FAS).
For medication adherence during each follow-up visit, the following four aspects are summarized:

1. Calculate the number of cases and percentage of each category of timely medication adherence for antidiabetic drugs since the last visit (never missed, rarely missed (no more than 3 times per week), frequently missed (3 or more times per week), almost never taken, and overdose).
2. Calculate the percentage of adherence and perform descriptive statistics on participants' adherence. Summarize the number of cases and percentages for each adherence category (<80%, 80%-120%, >120%).
3. Use the ATC4 classification according to the WHODrug GLOBAL (B3) C [V2024MAR] coding system to calculate the number of cases and percentages of antidiabetic drugs used at each visit, and provide a summary by center.
4. Using the ATC4 classification of WHODrug GLOBAL (B3) C [V2024MAR], calculate the number and percentage of cases for each category of polypharmacy (monotherapy, dual therapy, triple therapy) for antidiabetic drugs at each visit, and provide a summary by center. If the ATC4 classification is an oral combination antidiabetic drug, it should be counted as dual therapy.

List the medication usage list for diabetes treatment and the diabetes treatment regimen list.

7.4 Efficacy Analysis

7.4.1 Primary Endpoint Analysis

Analysis will be conducted using both the Full Analysis Set (FAS) and Per Protocol Set (PPS).
Calculate the number of participants, percentage, and 95% CI of participants with HbA1c < 7% at visit 5 (baseline 84 ± 3 days) in the intervention group and control group, respectively. Calculate the 95% CI of the difference in proportions between the two groups (intervention group - control group). Use the chi-square test or Fisher's exact probability test to compare the proportions of participants with HbA1c < 7% between groups. The 95% CI was calculated using the Wald method.

Sensitivity analysis of primary efficacy endpoints: Using the CMH method that accounts for center effects, compare the proportion of subjects with HbA1c < 7% between groups.

List the subjects with HbA1c < 7% at Visit 5.

7.4.2 Secondary Endpoint Analysis

Analysis will be conducted using both FAS and PPS.

* **Proportion of participants with HbA1c < 6.5% at Visit 5 (baseline 84 ± 3 days)**

  Calculate the number of participants, percentage, and 95% CI of participants with HbA1c < 6.5% at Visit 5 (baseline 84 ± 3 days) in both the intervention group and the control group. Calculate the 95% CI of the difference in proportions between the two groups (intervention group – control group). Use the chi-square test or Fisher's exact probability test to compare the proportions of participants with HbA1c < 6.5% between groups.

  List the participants with HbA1c < 6.5% at Visit 5.

* **Proportion of participants with HbA1c < 6% at Visit 5 (baseline 84 ± 3 days)**

  Calculate the number of participants, percentage, and 95% CI of participants with HbA1c < 6% at Visit 5 (baseline 84 ± 3 days) in the intervention group and control group, respectively. Calculate the 95% CI for the difference in proportions between the two groups (intervention group - control group) and use the chi-square test or Fisher's exact probability test to compare the proportions of participants with HbA1c < 6% between the two groups.

  List the participants with HbA1c < 6% at visit 5.

* **Decrease in HbA1c at Visit 5 (baseline 84 ± 3 days).** Calculate the decrease in HbA1c for the intervention group and control group at visit 5 compared to the screening period, as well as the percentage change. Use t-tests or Wilcoxon rank-sum tests for intergroup comparisons. Among them, the percentage change in HbA1c at Visit 5 compared to the screening period = (HbA1c at Visit 5 - HbA1c at the screening period) / HbA1c at the screening period) × 100%.

* **Hypoglycemia Incidence and Frequency:**

  Calculate the number of episodes, total number of episodes, and percentage of participants in the intervention group and control group who experienced hypoglycemia during each visit (V3A—control group visit/V3B—intervention group visit, V4). For hypoglycemia incidence rates, use chi-square tests or Fisher's exact probability test for between-group comparisons.

  List the hypoglycemia episodes experienced by participants at each visit.

* **Changes in pancreatic β-cell function**
* **Changes in insulin resistance levels**
* **Body weight**

*** Waist circumference**

*** Changes in BMI**

For the above secondary efficacy endpoints, calculate the change values and percentage changes relative to the screening period at the end of treatment (V5). For continuous variables, use t-tests or Wilcoxon rank-sum tests for between-group comparisons.

Among these, Percentage change relative to the screening period at the end of treatment (V5) = (indicator results at visit 5 - indicator results at the screening period))/ indicator results at the screening period

The indicator results are the results of the above secondary efficacy endpoints.

7.5 Safety Analysis

7.5.1 Exposure Time: Not applicable.

7.5.2 Adverse Events (AEs)

Coding: All AEs will be coded using MedDRA/C [v27.0].

Summarize the number of cases, incidence rates, and frequency of adverse events, serious adverse events, adverse events related to drug therapy, serious adverse events related to drug therapy, and adverse events leading to withdrawal from the study that occurred during the research process.

Summarize adverse events, serious adverse events, adverse events related to drug therapy, serious adverse events related to drug therapy, and adverse events leading to withdrawal from the study according to SOC/PT and describe them in groups. If the same patient experiences multiple adverse events, count it as one case when calculating the incidence rate; if a patient experiences the same AE multiple times, count it as one case in the AE incidence rate calculation.

Severity of adverse events: Assess the severity of AEs as mild, moderate, or severe, and summarize the number of cases, incidence rate, and severity of adverse events for each severity level. If a subject experiences multiple AEs, the most severe AE is included in the analysis of the number of adverse events; if a subject experiences the same AE multiple times, the most severe occurrence is included in the analysis of the incidence rate for that severity level.

Adverse events related to drug therapy: Adverse events classified as “definitely related,” “likely related,” or “possibly related” to drug therapy.

Provide a summary table of adverse events by subcenter.

Provide a list of all types of adverse events.

7.5.3 Device Defects: Not applicable.

7.5.4 Laboratory Test Results

Conduct a statistical description of the quantitative results of laboratory tests (glucose-related tests, complete blood count, liver and kidney function, lipid profile) for screening visits and visit 5, as well as any changes from the screening

period. Classify pre-treatment and post-treatment laboratory test results into the following categories: clinically significant abnormalities, non-clinically significant abnormalities, normal, and not tested, in that order. Then generate a conversion table.

List all laboratory test results.

7.5.5 Electrocardiogram (ECG): Not applicable.

7.5.6 Other Safety Assessments

***Physical examination**

Descriptive statistics were performed on the height of participants during the screening period. For the remaining indicators, namely systolic blood pressure, diastolic blood pressure, and pulse rate, descriptive statistics were performed on the data from each visit. Since descriptive statistical analysis of weight, waist circumference, and BMI had already been conducted in the secondary endpoint indicators, no summary is provided here. A list of physical examination items for participants is provided.

***GA measurement**

Descriptive statistics were performed on GA measurement results at each visit, specifically the changes from the screening period.

List the GA measurement results at each visit. For the V3A-control group visits and V5-follow-up period, list the clinical assessment results of GA measurements (normal, abnormal without clinical significance, abnormal with clinical significance, not examined).

***Pregnancy examination** List the subjects with positive pregnancy results.

7.6 Other Analyses: Not applicable.

7.7 Changes to the Planned Analyses

1. Changes in pancreatic β-cell function, insulin resistance levels, body weight, waist circumference, and BMI: Calculate the change in values at the end of treatment (V5) relative to the screening period. This has been changed to calculating both the change in values and the percentage change at the end of treatment (V5) relative to the screening period.
2. Add the statistical analysis of the proportion of patients with HbA1c <6% at Visit 5 (baseline 84 ± 3 days) to the secondary endpoint measures.

8. References

[a] National Medical Products Administration (NMPA). Good Clinical Practice for Medical Device Clinical Trials. May 2022.

[b] Guidelines for Biostatistics in Drug Clinical Trials. June 2016.

[c] Guidelines for Data Management and Statistical Analysis Plans in Drug Clinical Trials. Announcement No. 63, 2021.

9. Statistical Chart Templates

Refer to the attached file “Asahi Kasei_GA_TFL_Mock shell_V1.0-20241009” and generate an independent file.

10. Data Set Programming INSTRUCTIONS

Refer to the attached file “Asahi Kasei_GA Project ADS Programming Specifications” and generate an independent file.