# Statistical result report: ver 1.0

**Study title**:
Trial Efficacy of Saisei Pharma Dietary Supplements MAF Capsules,
148 mg and M Capsules, 148 mg in Hospitalized COVID-19 Patients (SaiseiCovUKR)

**Version No.**: ver 1.0 2021/ 9 / 6

**Contents**:



**Software**: SPSS 24.0 for windows


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Update history :

| version | date | Contents |
|---|---|---|
| 1.0 | 2021 / 9 / 6 | First edition |
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# 1. Patients characteristics (Age)

| | Group | | | ASD |
|---|---|---|---|---|
| | K<br>Standard | M<br>MAF-capsules | W<br>M-capsules(whey) | |
| n | 72 | 63 | 69 | |
| Age | | | | |
| mean ± SD | 63.6 ± 10.7 | 63.5 ± 10.5 | 63.6 ± 10.7 | 0.005 |
| median [IQR] | 65.0 [56.0, 72.0] | 65.0 [56.0, 71.0] | 64.0 [57.5, 70.5] | |
| range (min - max) | 38.0 — 87.0 | 34.0 — 83.0 | 38.0 — 90.0 | |

SD: standard deviation; IQR: inter quatile range [25%, 75%]
ASD: Absolute standardized difference

**●Aim**

To show the descriptive statistics of age in each group.

**●Methods**

To evaluate whether balance is ensured by random assignment by calculating absolute standard deviation (ASD).

**●Results**

The ASD was less than 0.1, indicating that age balance was ensured in the three groups.

# 2. Steroid use

| | Group | | | P-value (vs. Group K) | |
|---|---|---|---|---|---|
| | K | M | W | | |
| | Standard | MAF-capsules | M-capsules(whey) | Group M | Group W |
| n | 72 | 63 | 69 | | |
| Steroid use | 49 , 68.1 | 33 , 52.4 | 39 , 56.5 | 0.078 | 0.169 |
| Dexamethasone use | 45 , 62.5 | 28 , 44.4 | 39 , 56.5 | **0.040** | 0.496 |
| Methylprednisolone use | 4 , 5.6 | 5 , 7.9 | 0 , 0.0 | 0.733 | 0.120 |

P-value: Fisher's exact test.

**●Aim**

A comparison will be made between the intervention drugs on the steroid use. For group comparisons, we will compare group M and group W against group K. Each hypothesis (K vs. M, K vs. W) will be assumed to be independent, and no correction for multiplicity will be made

**●Methods**

Fisher's exact test was used to compare the steroid use to Group K.

**●Results**

We observed a trend toward lower frequency of Steroid use in Group M compared to Group K (P=0.078). In particular, a statistically significant difference was detected in the frequency of Dexamethasone use, indicating that it is used less frequently in Group M (P=0.040).

# 3. Primary outcome

## 1) 29-day Participant Mortality

| | Group | | | P-value (vs. Group K) | |
|---|---|---|---|---|---|
| | K<br>Standard | M<br>MAF-capsules | W<br>M-capsules(whey) | Group M | Group W |
| n | 72 | 63 | 69 | | |
| Outcome | | | | | |
| 29-day Mortality (n, %) | 11 , 15.3 | 2 , 3.2 | 3 , 4.3 | **0.020** | **0.046** |

P-value: Fisher's exact test.

**●Aim**

A comparison will be made between the intervention drugs on the incidence of death. For group comparisons, we will compare group M and group W against group K. Each hypothesis (K vs. M, K vs. W) will be assumed to be independent, and no correction for multiplicity will be made

**●Methods**

Fisher's exact test was used to compare the incidence of death to Group K.

**●Results**

There was a statistically significant reduction in mortality in Group M and Group W compared to Group K.

# 3. Primary outcome

## 2) Days-hospitalization

| | Group | | | P-value (vs. Group K) | |
|---|---|---|---|---|---|
| | K | M | W | | |
| | Standard | MAF-capsules | M-capsules(whey) | Group M | Group W |
| n | 72 | 63 | 69 | | |
| Days-hospitalisation (day) | | | | | |
| mean ± SD | 13.9 ± 3.8 | 13.7 ± 3.4 | 13.7 ± 4.1 | | |
| median [IQR] | 14.0 [13.0, 15.0] | 13.0 [12.0, 15.0] | 13.0 [12.0, 14.0] | 0.166 | 0.056 |
| range (min - max) | 2.0 — 23.0 | 8.0 — 24.0 | 7.0 — 34.0 | | |
| Days-hospitalisation (day)_Excluding deaths | | | | | |
| mean ± SD | 14.2 ± 3.1 | 13.8 ± 3.4 | 13.4 ± 3.3 | | |
| median [IQR] | 14.0 [13.0, 15.0] | 13.0 [12.0, 15.0] | 13.0 [12.0, 14.0] | 0.064 | **0.017** |
| range (min - max) | 7.0 — 23.0 | 8.0 — 24.0 | 7.0 — 26.0 | | |

SD: standard deviation; IQR: inter quatile range [25%, 75%]
P-value: Mann-Whitney U test

**●Aim**

A comparison will be made between the intervention drugs for the duration of hospitalization. For group comparisons, we will compare group M and group W against group K. Each hypothesis (K vs. M, K vs. W) will be assumed to be independent, and no correction for multiplicity will be made

**●Methods**

The Mann-Whitney U test was used to compare the duration of hospitalization for Group K (no normality assumption was made).

**●Results**

Compared to Group K, Group M and Group W showed a trend toward a decrease but in statistical non-significance.

When fatal cases were excluded and the analysis was performed by replacing the term "recovery" with "time to recovery," a statistically significant decrease in time to recovery was observed in Group W compared to Group K (an average decrease of about 0.8 days).

# 4. Secondary outcome

## 1) Duration of oxygen therapy (day)

| | Group | | | P-value (vs. Group K) | |
|---|---|---|---|---|---|
| | K | M | W | | |
| | Standard | MAF-capsules | M-capsules(whey) | Group M | Group W |
| n | 72 | 63 | 69 | | |
| Duration of oxygen therapy (day) | | | | | |
| mean ± SD | 9.9 ± 5.1 | 7.9 ± 5.2 | 7.8 ± 5.8 | | |
| median [IQR] | 9.0 [5.3, 13.0] | 6.0 [4.0, 11.0] | 6.0 [4.0, 10.5] | **0.020** | **0.004** |
| range (min - max) | 2.0 — 23.0 | 0.0 — 24.0 | 1.0 — 33.0 | | |
| Duration of oxygen therapy (day)_Excluding deaths | | | | | |
| mean ± SD | 9.5 ± 4.9 | 7.8 ± 5.1 | 7.4 ± 4.9 | | |
| median [IQR] | 8.0 [5.0, 12.0] | 6.0 [4.0, 10.5] | 6.0 [3.8, 9.3] | **0.030** | **0.006** |
| range (min - max) | 2.0 — 21.0 | 0.0 — 24.0 | 1.0 — 22.0 | | |

SD: standard deviation; IQR: inter quatile range [25%, 75%]
P-value: Mann-Whitney U test

**●Aim**

A comparison will be made between the intervention drugs for the duration of oxygen therapy. For group comparisons, we will compare group M and group W against group K. Each hypothesis (K vs. M, K vs. W) will be assumed to be independent, and no correction for multiplicity will be made

**●Methods**

The Mann-Whitney U test was used to compare the duration of oxygen therapy for Group K (no normality assumption was made).

**●Results**

A statistically significant decrease was observed in Group M and Group W compared to Group K (2.0 - 2.1 days shorter on average).

As a sensitivity analysis, we also present the results of the analysis excluding fatalities, which showed similar results.

# 4. Secondary outcome

## 2) Admission: Invasive_ventilation, Noninvasive_ventilation, ICU

| | Group | | | P-value (vs. Group K) | |
|---|---|---|---|---|---|
| | K | M | W | | |
| | Standard | MAF-capsules | M-capsules(whey) | Group M | Group W |
| n | 72 | 63 | 69 | | |
| Invasive_ventilation admission | 9 , 12.5 | 2 , 3.2 | 1 , 1.4 | 0.061 | **0.018** |
| Noninvasive_ventilation admission | 14 , 19.4 | 6 , 9.5 | 4 , 5.8 | 0.145 | **0.022** |
| ICU admission | 12 , 16.7 | 6 , 9.5 | 3 , 4.3 | 0.311 | **0.027** |

P-value: Fisher's exact test.

**●Aim**

A comparison will be made between the intervention drugs on the admission of invasive ventilation, non-invasive ventilation and ICU. For group comparisons, we will compare group M and group W against group K. Each hypothesis (K vs. M, K vs. W) will be assumed to be independent, and no correction for multiplicity will be made

**●Methods**

Fisher's exact test was used to compare the admission rate to Group K.

**●Results**

There was a statistically significant decrease in the frequency of use of artificial respiration (invasive and non-invasive) and ICU in Group W compared to Group K.

In addition, although statistically non-significant, there was a trend toward a decrease in the frequency of artificial respiration (invasive and non-invasive) and ICU use in Group M compared to Group K.