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

ClinicalTrials.gov Identifier: NCT04762628

Recruitment Status : Active, not recruiting

First Posted : February 21, 2021

Last Update Posted : February 24, 2021

Brief Summary:

The SaiseiCovUKR clinical study is a multicentric, randomize trail study targeting hospitalize with COVID-19 patients who not requiring the mechanical ventilation. This study aims to provide preliminary data on the activity and safety of MAF capsules and M capsules in the target population after 14 days of dosing. MAF capsules and M capsules are dietary supplements targeting gut's mucosal immunity to control local and systemic inflammation, limiting epithelial damage and prevent the accumulation of pathological macrophage populations in sites of SARS-CoV-2 infection.

Condition or disease	Intervention/treatment	Phase
Covid19	Dietary Supplement: MAF capsules 148 mg Dietary Supplement: M capsules 148 mg Other: Standard of care	Not Applicable

Detailed Description:

SaiSei Pharma is developing biologics using an enzymatical modification Vitamin D binging protein and other glycoproteins in biological substrates, which shown to in increase macrophages phagocytic and antigen processing activity without promoting proinflammatory profile on macrophages. Bovine colostrum is substrate MAF capsules and bovine whey for M capsules. Enteric capsules formulation of investigational dietary supplements targeting gut mucosa and its associated natural anti-inflammatory macrophages profile. The SaiseiCovUKR clinical study is multicentric, randomize, open-label in hospitalized with moderate and severe COVID-19 participants to provide data on the activity and safety of MAF capsules and M capsules in the target population after 14 days of dosing. The trial will use an adaptive design based on pre-specified criteria, using an independent external Data Monitoring Committee (DMC) to monitor safety, efficacy, and review data at appropriate intervals. The general objectives of the study are to obtain preliminary indication of activity of MAF capsules and M capsules on shortening time to the recovery and decreasing mortality in the target population (600 patients, age ≥ 18 years). The study results can provide a background for further investigation of studied dietary supplements as new drugs in COVID-19.

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	600 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Randomized Trial to Assess the Efficacy and Safety of Dietary Supplements **MAF Capsules**, 148 mg and M **Capsules**, 148 mg in Addition to the Standard of Care (SOC) Compared SOC in the Treatment of Hospitalized With COVID-19 Patients Who Not Requiring the Mechanical Ventilation
Actual Study Start Date :	October 27, 2020
Estimated Primary Completion Date :	November 1, 2021
Estimated Study Completion Date :	January 10, 2022