

Study of the Efficacy and Safety for Rituximab in Myalgia Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

NCT06952413

Status	RECRUITING
Phase	Phase 2
Sponsor	National Center of Neurology and Psychiatry, Japan
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (5)

- Patients diagnosed with ME/CFS who meet the Canadian criteria by a physician.
- Patients with a severity score of 4 or higher on the Performance Status (PS) based ME/CFS severity classification by the Ministry of Health, Labour and Welfare Research Group
- Patients who are between 18 and 65 years of age at the time of obtaining written consent
- Patients who can be hospitalized (hospitalized from the day before administration and discharged the day after administration) at the time of the first dose of each of the primary and secondary evaluation periods
- Patients whose written consent has been obtained

Exclusion (21)

- Patients with a history of severe hypersensitivity or anaphylactic reactions to components of rituximab or products derived from mouse protein
- Patients whose cardiopulmonary function is judged by the treating physician to be not maintained
- Patients complaining of fatigue that does not meet the diagnostic criteria for ME/CFS
- Patients found to have other medical conditions that may cause symptoms
- Patients who are pregnant, lactating, or have a positive pregnancy test (serum human chorionic gonadotropin test) at the time of enrollment

... and 16 more (see full listing online)

Locations (1 total)

National Center of Neurology and Psychiatry, Kodaira, Tokyo, Japan