Rituximab EfFicacy IN MyasthEnia Gravis (REFINE)

NCT05868837

Status	RECRUITING
Phase	Phase 3
Sponsor	Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (6)

- a. Positive serologic test for anti-AChR or anti-MuSK antibody titers as confirmed at screening (one retest allowed), and
- At least one of the following:
- i)-History of abnormal neuromuscular transmission test results demonstrated by single- fiber electromyography or repetitive nerve stimulation; or ii)-History of positive anticholinesterase test (eg, edrophonium chloride test); or iii)-Patient demonstrated improvement in MG signs on oral cholinesterase inhibitors, as assessed by the treating physician; or iv)-Clinical syndrome consistent with a diagnosis of MG, and not otherwise explained by another condition. c. MGFA Clinical Classification Class II, III, or IV at the time of screening and randomization.
- d. MG-ADL score of 5 or greater at screening and at randomization with \> 50% of this score attributed to non-ocular items. e. QMG score of 11 or greater at screening and at randomization. f. Willing and able to comply with the protocol, complete study assessments, and return for follow- up visits.
- g. Females of childbearing potential who are sexually active with a non-sterilized male partner must use at least one highly effective contraception method (Table 1) from the time of screening and for 12 months after the final dose of IP. Periodic abstinence, the rhythm method, and the withdrawal method are not acceptable methods of contraception. h. Females of childbearing potential are defined as those who are not surgically sterile (ie, bilateral tubal ligation, bilateral oophorectomy, or complete hysterectomy) or those who are not postmenopausal (defined as 12 months with no menses without an alternative medical cause).

... and 1 more (see full listing online)

Exclusion (23)

- Any condition that, in the opinion of the Investigator, would place the patient at unacceptable risk of complications, interfere with evaluation of the IP, or confound the interpretation of patient safety or study results.
- Lactating or pregnant females, or females who intend to become pregnant anytime from signing the informed consent form (ICF) throughout the RCP plus 6 months following last dose of IP.
- History of drug or alcohol abuse within \< 1 year prior to screening, or any condition associated with poor compliance as judged by the Investigator.
- Site staff and their family members.
- Currently committed to an institution by way of official or judicial order.

... and 18 more (see full listing online)

Locations (1 total)

Policlinico A. Gemelli IRCCS, Roma, Italy