

# Efficacy and Safety of Pozelimab and Cemdisiran Combination Therapy in Patients With Sporadic Inclusion Body Myositis

NCT06479863

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Status	RECRUITING
Phase	Early Phase 1
Sponsor	Austin Neuromuscular Center
Enrollment	10 participants

## Key Eligibility Criteria

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### Inclusion (17)

- \. Age e45 years to 75 years of age 2. Diagnosed with sIBM based on the ENMC IBM Research Diagnostic Criteria 3. Willing and able to comply with clinic visits and study-related procedures. 4. Provide informed consent signed by the study patient or legally acceptable representative.
- \. Able to understand and complete study-related questionnaires. 6. Able to ambulate at least 20 ft/6 meters with or without assistive device Once arising from the chair, the participant may use any walking device, i.e. walker/frame, cane, crutches, or braces. They cannot be supported by another person and cannot use furniture or walls for support.
- \. If female, the subject must be: (a) surgically sterilized via hysterectomy, bilateral oophorectomy, or bilateral tubal ligation. or (b) of childbearing potential and using a birth control method, such as:
- o Combined (estrogen and progesterone-containing) hormonal. contraception associated with inhibition of ovulation:
- o Oral

... and 12 more (see full listing online)

### Exclusion (7)

- \. Other neurological conditions (e.g., hemiplegia post-stroke, Parkinson's Disease) or musculoskeletal conditions (e.g., severe osteoarthritis) causing mobility impairment.
- \. Any known active malignancy 3. Significant illness or history of significant illness that, in the investigator's opinion, may adversely affect the patient's participation in this study.
- \. Any previous treatment with a complement inhibitor 5. History of meningococcal disease 6. No documented meningococcal and pneumococcal vaccination within 5 years prior to screening visit unless vaccination will be administered during the screening period and prior to initiation of study treatment.
- \. Known contraindication to meningococcal (group ACWY conjugate and group B vaccines) and pneumococcal vaccines.
- \. Subject unwilling to receive meningococcal and pneumococcal vaccinations. 9. Patients with screening serum ALT levels  $\geq 3 \times \text{ULN}$  and/or total bilirubin  $\geq 2 \times \text{ULN}$  (unless bilirubin elevation is due to suspected Gilbert's syndrome).

... and 2 more (see full listing online)

## Locations (2 total)

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Austin Neuromuscular Center, Austin, Texas, United States  
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<https://clinicaltrials.gov/study/NCT06479863>

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