Assessing Quality Measures in Multiple Sclerosis Patients With Initiation of Dalfampridine

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BACKGROUND

Clinical studies suggest that use of dalfampridine in patients diagnosed with Multiple Sclerosis (MS) is associated with improvements in visual function, strength, ambulation, fatigue, and endurance. Ambulatory impairment is a key feature of MS and indicative of disease progression. A previous phase 2/3 study showed significant improvement in walking ability in MS patients which was sustained over a 14 week period. This study is designed to further define improvement in ambulation besides speed which include quality of life, confidence in daily activity performance, balance and gait. MS patients using dalfampridine therapy are often assessed for improvement relative only to their change in walking speed. However, from our experience with these patients we have noticed that there may be a variety of quality measures related to the walk that may show improvement when the change in speed remains consistent after initiation of dalfampridine. In addition to the T2SFV, we are seeking to measure improvements in areas such as balance, confidence, quality of life, and fall risk. We are seeking a more complete view of the patients’ ambulation patterns and improvements with initiation of dalfampridine therapy.

INCLUSION CRITERIA

1. Definitive diagnosis of MS (RRMS, SPMS, PPMS) made at least 3 months prior to screening.
2. Appropriate candidate for dalfampridine use (per investigator review of patient history).
3. Not received any formulation of dalfampridine in the previous 3 months prior to screening/baseline visit.
4. Deemed by the investigator to be eligible for dalfampridine therapy
   I. Creatinine clearance >50mL/min
   II. No history of seizures
   III. No history of moderate or severe renal impairment
5. EDSS ≤ 6.5 at baseline
6. Able to walk 14 meters on repeated occasions
7. Ability to remain free of any concomitant medications or procedures that may interfere with the objectives of the study
8. Stable on current disease modifying therapy, if applicable
9. Clinical stability at least 30 days prior to screening
10. No previous reaction to the study medication (dalfampridine)
11. Between 18-75 years of age, inclusive

STUDY DESIGN

Observational, Prospective, Interventional

METHODOLOGY

Eligible patients must not have received any form of dalfampridine in the prior 3 months and not on medications that could interfere with the objectives.

OBJECTIVE

PRIMARY:
To assess for an association between the measured speed (T2SFV) and other measures that capture quality and confidence while walking.

SECONDARY:
To assess for an improvement in patient quality of life, observe changes in patient gait patterns.

EXCLUSION CRITERIA

1. Deemed not appropriate for use of dalfampridine
2. Permanent use of a wheelchair
3. Not appropriate for study at discretion of PI concerning patient compliance, etc.
4. Currently on concomitant medications that may have an effect in combination with Ampyra or on balance and ambulation, unless the PI deems that the patient is stable on the concomitant medication and changes in the measured objectives would most likely not be impacted by the use of the concomitant medication.

PATIENT ASSESSMENTS

Completion of:
- MSQOL-54 (Multiple Sclerosis Quality of Life)
- Activities-specific Balance Confidence Scale (ABC-S)
- Self Selected walking speed
- MSWS-12 (Multiple Sclerosis Walking Scale)