BACKGROUND

- Ocriplasmin was approved by the FDA on October 17, 2012 for the treatment of symptomatic vitreomacular adhesion following 2 MVI-TRUST Phase II clinical trials.
- In case reports, ocriplasmin has been associated with abnormal full-field electroretinograms (fERGs) and multifocal ERGs in patients with symptomatic vitreomacular adhesion (VMA).
- ERGs were not regularly obtained in the MVI-TRUST trials, making the incidence of ERG reductions following ocriplasmin treatment difficult to calculate.
- To evaluate the relationship of ERG changes with anatomic and visual outcomes for up to 24 months after a single injection of ocriplasmin 0.125 mg in the OASIS trial.

METHODS: STUDY DESIGN AND OBJECTIVES

- OASIS Study Design and Objective: 24-month, Phase IIIb, randomized, sham-controlled, double-masked, multicenter clinical trial evaluating ocriplasmin in subjects with symptomatic VMA.
- ERG Substudy Objective: Correlation of VMA resolution and BCVA with fERG from baseline through Month 24.

RESULTS

- Resolution of Acute Expert-Defined ERG Amplitude Reductions in Ocriplasmin and Sham Groups
- VMA Resolution by ERG Amplitude Reductions in Ocriplasmin and Sham Groups
- Subjects With Unresolved VMA Amplitude Reductions by Study End

CONCLUSIONS

- The prospective nature of the ERG substudy allowed for standardization and comparison of changes from baseline, not possible with retrospective cases.
- Less than half (40.0%) of ocriplasmin-treated subjects experienced acute ERG reductions.
- 92.5% of subjects receiving ocriplasmin had either normal ERGs or resolution of ERG reductions by study end.
- Only 1 of 3 subjects not resolved by study end experienced a loss of visual acuity.
- An abnormal ERG is associated with a higher rate of VMA release compared to a normal ERG.
- ERG reductions following VMA release may be related to photoreceptor trauma and may parallel commotio retinae.
- Short-term assessments of ERGs and BCVA do not reflect ultimate visual acuity outcome of treatment with ocriplasmin over a longer time period.

REFERENCES


DISCLOSURES AND ACKNOWLEDGMENTS

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