Background

Are novel complications seen in long-term highly treatment experienced cohorts?

Do complications change over time?

Are complications different in a more disabled, treatment-refractory cohort?

We describe the prevalence and types of hospitalizations, serious infections, autoimmunity and malignancy.

This data was not collected in phase III trials but in “real-world” high disability, treatment-refractory, high disability, MS patients.

Results

41 Serious adverse events, nearly entirely hospitalizations, occurred at a rate of 0.16 events per PY; only 1 for MS relapse. Serious events differed for LT 0.35/PY and ST 0.06/PY. Serious infections caused 16 hospitalizations, 0.063/PY.

Malignancy

Other Infection:

Other infection: post-op MRSA osteomyelitis 1

Prior Treatment Experience:

Experience

History

Histoplasmosis

Histoplasma capsulatum, a dimorphic fungus, is endemic where human, soil acidity, and bird/droppings promote growth. Contact with mycelial in soil and caviess aerosselize the microconidia, infecting humans as granulomas containing encapsulated budding yeast. Positive histoplasmin skin tests occur in as many as 90% of the people living in areas where H. capsulatum is common, such as the eastern and central United States, causing an estimated 500,000 pulmonary infections a year. Infecion is treated with ito and oral antifungals.


Conclusions

We report serious events in an aggressively treated high disability, treatment-refractory clinic cohort, with long-term use of ALE.

• Autoimmunity is fairly stable over time.

• SAE were infrequent, occurring in a small minority

• Serious infections were infrequent, although some unusual.

• Serious infection rate declined over time.

• No malignancy signal was appreciated.

Histoplasmosis has not been previously described, but is not surprising.

• MS hospitalizations were rare.