Tolerance and Safety of Benznidazole in a U.S.-based Chagas Adult Population

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BACKGROUND

- The U.S. has the 7th highest number of Chagas Disease (CD) cases worldwide (~300,000), based on sero-prevalence and epidemiologic study8, however limited data exist on treatment effects in this population.
- There are data to support treatment in the chronic phase8, however the first-line agents, benznidazole and nifurtimox, have a high rate of toxicity.
- Benznidazole is available from the CDC by research protocol at 5-mg/kg/day for 60 days
- The Center of Excellence for Chagas Disease (CECD) at Olive View-UCLA Medical Center has acquired a patient panel of nearly 300 patients with chronic Chagas disease

OBJECTIVE

- Evaluate the safety and tolerability of benznidazole in an adult US-based population

METHODS

- Observational cohort study of 26 patients in the indeterminate or chronic stage of CD
- Diagnostic confirmation with EIA and IFA, using TESA as a tiebreaker
- Study period: February, 2011- April, 2013
- Intervention: benznidazole 5mg/kg/day for 60 days
- Follow-up: every 2 weeks during therapy, 1 month post-therapy, and at 1 year.

RESULTS

- Adverse events graded by the NIH Common Terminology Criteria for Adverse Events V. 4.0

DISCUSSION

- We found 3 cases of Angioedema (a rarely reported complication of benznidazole) which was associated with a higher body weight and total daily dose
- Neuropathy was a late complication of therapy that was debilitating in 4 cases, leading to disability in 2, and often lasting >6 months
- Pinazo et al83 noted in a largely Bolivian immigrant population in Spain (N=105) similar completion rates (84%), less neuropathy (29%) [debilitating neuropathies not quantified], less nausea (2%), and otherwise a similar occurrence of rash (50%), headache (56%), and anorexia (40%)

IMPLICATIONS

- Providers need to be aware and patients need to be informed of the distinct possibility of angioedema
- Neuropathy can be debilitating and requires further clinical study to identify risk factors and more favorable regimens to optimize the benefit of treatment in the chronic phase

Figure 1: Demographics

Figure 2: Adverse Events

Figure 3: Adverse Events and Age, Weight, Gender

Figure 4: Rash and Angioedema

REFERENCES