

8.2 Masking in Lyme Disease Trial

Lyme disease is an infection with a spirochete bacterium acquired from a tick bite. Most patients recover after antibiotic treatment of the acute infection, but some can develop chronic symptoms, or "post Lyme syndrome," one symptom of which can be severe fatigue. The STOP-LD trial {Krupp, 2003} was a randomized, double-blind trial of a long course of IV ceftriaxone (an antibiotic) to treat post Lyme syndrome.

The results section includes:

Masking. At ... 6 months 69% (18/26) of the ceftriaxone vs 32% (7/22) of the placebo group correctly guessed their treatment assignment ($p = 0.004$).

In the discussion they wrote:

"The observation that more of the ceftriaxone than placebo treated groups correctly guessed their treatment assignment could mean that masking [blinding] may have been compromised."

Does the comparison above ($P=0.004$) support the authors' concern that masking may have been compromised? Explain. [Hint: think carefully about what is being compared before answering!]