

论著

三苯双脒肠溶片治疗1 292例肠道线虫感染者IV期临床试验

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摘要

目的 进一步评价三苯双脒肠溶片治疗成人钩虫和蛔虫感染的安全性和疗效。方法 在海南、四川和贵州等3个临床试验中心进行开放临床试验, 受治者经改良加藤法(Kato-Katz)粪检确诊为钩虫、蛔虫或合并其他肠道蠕虫感染, 共收治15岁以上感染者1 292例。蛔虫感染组顿服三苯双脒肠溶片300 mg, 钩虫感染、钩虫和蛔虫混合感染及钩虫和(或)蛔虫合并其他肠道蠕虫感染组顿服三苯双脒肠溶片400 mg, 观察不良反应。于治疗后3~4周进行粪便1送3检考核疗效。结果 三苯双脒肠溶片对钩虫感染者的治愈率及有效率分别为88.4%(1 009/1 141)和99.1%(1 131/1 141); 对蛔虫感染者的治愈率及有效率分别为95.0%(419/441)和99.8%(440/441); 对鞭虫感染者的治愈率为76.8% (109/142)。三苯双脒的不良反应发生率为3.3%(42/1 292), 不良反应程度轻和短暂, 对血、尿常规, 肝、肾功能和心电图无明显影响。结论 扩大人群临床试验进一步验证三苯双脒肠溶片治疗钩虫、蛔虫、鞭虫和其他蠕虫感染具有较好疗效, 所用剂量安全。

关键词 [三苯双脒肠溶片](#) [钩虫](#) [蛔虫](#) [鞭虫](#) [安全性](#)

分类号

Tribendimidine Enteric Coated Tablet in Treatment of 1 292 cases with Intestinal Nematode Infection -- a Phase IV Clinical Trial

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Abstract

Objective To further evaluate the efficacy and safety of tribendimidine in treatment of adult patients with intestinal nematode infections. Methods An open and multi-center clinical trial was conducted in the provinces of Hainan, Sichuan and Guizhou. A total of 1 292 infected cases aged 15-70 years were enrolled in the study. Modified Kato-Katz method was used to diagnose the cases with intestinal nematode infections and assess the efficacy 3-4 weeks post treatment. Patients with *Ascaris lumbricoides* infection were treated orally with tribendimidine enteric coated tablets at a single dose of 300 mg, while in the patients with *Ancylostoma duodenale*, mixed *A. duodenale* and *A. lumbricoides*, or with other helminth infections, a single dose of 400 mg was administered. Results The cure rate and effective rate of the patients with *Ancylostoma* infection were 88.4% (1 009/1 141) and 99.1% (1 131/1 141), respectively, while in patients with *A. lumbricoides* infection, they were 95.0% (419/441) and 99.8% (440/441), respectively. The cure rate of tribendimidine enteric coated tablet given to patients with *Trichuris trichiura* infection at a single dose of 400 mg was 76.8% (109/142). The adverse effect induced by tribendimidine was light and transient with a rate of 3.3% (42/1 292). No apparent impact was seen on blood and urine routine examinations, hepatic and renal functions as well as ECG examination. Conclusion It is further confirmed that under the used dosage for expanding treatment in larger sample of patients with various ages and infected with *Ancylostoma duodenale*, *A. lumbricoides* and other helminthes, tribendimidine enteric coated tablet is safe with satisfactory efficacy.

Key words [Tribendimidine](#) [Ancylostoma duodenale](#) [Ascaris lumbricoides](#) [Trichuris trichiura](#) [Safety](#)

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