口服重组人干扰素α2b治疗小儿轮状病毒性肠炎的多中心、随机、双盲、安慰剂对照研究

潘家华，羊礼荣2，韩旻3，周浩泉1，祖庆1，周晓丽1，顾倩2，杨晓光2，王子斌3，李玉桂3

(1.中国科技大学第一附属医院，安徽合肥 230001;2.池州市人民医院，安徽池州 247000; 3.蚌埠第三人民医院，安徽蚌埠 233000)

摘要:

目的：评估口服重组人干扰素α2b（rhIFNα2b）治疗小儿轮状病毒性肠炎的有效性和安全性。方法：采用多中心、随机、双盲、安慰剂对照的临床研究方法，于2016年11月至2018年6月期间参加本研究的三家单位共收集符合入组条件的轮状病毒肠炎患儿90例，所有患儿均按照入院时间顺序随机编入安慰剂对照组、小剂量IFNα2b组和大剂量IFNα2b组。所有患儿在常规治疗基础上，安慰剂对照组患儿空腹口服阴性对照药（安慰剂），2次/天，共3天，小剂量IFNα2b组患儿空腹口服rhIFNα2b，每次20万IU/kg，2次/天，共3天；大剂量IFNα2b组患儿空腹口服rhIFNα2b，每次40万IU/kg，2次/天，共3天。所有患儿观察7 d，比较三组患儿治疗第3天以及第5天的临床疗效以及症状和体征消失时间，并评估口服rhIFNα2b的安全性。结果：90例患儿均完成研究，其中安慰剂对照组30例、口服小剂量IFNα2b组30例和口服大剂量IFNα2b组30例。三组患儿的年龄、体质量、性别、治疗前腹泻时间和脱水症状评分等情况比较差异均无统计学意义（P>0.05）；口服大剂量IFNα2b组第3 天和第5 天的显效率分别为86.7%和100%，显著高于口服小剂量IFNα2b组的53.3%和80.0%和安慰剂对照组的10.0%和63.3%（P<0.01），口服小剂量IFNα2b组第3 天的显效率又显著高于安慰剂对照组，差异具有统计学意义（P<0.05）。口服大剂量IFNα2b组和小剂量IFNα2b组患儿发热消退时间、呕吐消失时间和腹泻消失时间均显著短于安慰剂对照组（P<0.05）；而大剂量IFNα2b组在发热消退时间、腹泻消失时间和呕吐消失时间方面显著短于小剂量组（P>0.05）。口服大剂量IFNα2b组第3天大便轮状病毒抗原阴转率为43.3%，显著高于口服小剂量IFNα2b组的13.3%和对照组的6.7%，但治疗第5天三组大便轮状病毒抗原阴转率差异无统计学意义（P>0.05）。治疗期间未发现明显不良反应。结论：口服干扰素α2b治疗小儿轮状病毒性肠炎临床疗效好，且其临床疗效具有一定的剂量相关性，值得临床进一步探索和推广应用。

关键词: 肠炎 轮状病毒 干扰素α2b 口服途径 不同剂量 小儿
DOI: doi:10.13407/j.cnki.jpp.1672-108X.2019.01.002
基金项目:

A Multicenter, Randomized, Double-Blind and Placebo-Controlled Clinical Trial of Oral Recombinant Human Interferon α2b on Pediatric Patients with Rotavirus Enteritis

Pan Jiahua1 , Yang Lirong2, Han Min3, Zu Qing1 ,Zhou Lequan1 ,Zhou Xiaoli1 ,Gu Qian2 ,Yang Xiaoguang2, Wang Zibin3,Li Yugui3
(1. The First?Affiliated?Hospital?of?University?of?Science?and?Technology?of?China, Anhui Hefei 230001, China; 2. The People's Hospital of Chizhou, Anhui Chizhou 247000, China; 3. The Third People's Hospital of Bengbu, Anhui Bengbu 233000, China)

Abstract:

Objective: To evaluate the effect and safety of oral recombinant human interferon α2b (rhIFNα2b) on children with rotavirus enteritis. Methods A multicenter, randomized, double-blind and placebo-controlled clinical trial was carried out in three hospitals from November 2016 to May 2018. According to the time of admission, 90 children with confirmed rotavirus enteritis were prospectively and randomly divided into oral placebo control group in 30 cases, oral small-dose rhIFNα2b group in 30 cases and oral large-dose rhIFNα2b group in a double-blind manner. All of children with rotavirus enteritis were received conventional treatment, while those in control group oral placebo twice a day for three days in addition, those in the oral small-dose rhIFNα2b group oral rhIFNα2b (0.2 MIU/kg·times) twice a day for three days in addition, those in the oral large-dose rhIFNα2b group oral rhIFNα2b (0.4 MIU/kg·times) twice a day for three days in addition. All children were observed for seven days. The statistics was analyzed by SPSS 19.0 software. The therapeutic effect was evaluated at 3 and 5 days after therapy and clinical symptoms and signs continuous time among three groups were compared. The safety of oral rhIFNα2b was evaluated during treatment. Result: All of 90 children completed the study, included 30 cases in placebo control group, 30 cases in oral small dose IFNα2b group and 30 cases in oral large dose IFNα2b group. There were no statistically significant differences in age, weight, gender, duration of diarrhea before treatment, and scores of dehydration symptoms of the children in three groups (P>0.05). The cure efficiency of the 3rd and 5rd in the oral large-dose IFNα2b group were 86.7% and 100.0%, respectively, significantly higher than the 53.3% and 80.0% in the oral small-dose IFNα2b group and 10.0% and 63.3% in the placebo control group (P<0.01). The cure efficiency of 3d and 5d in the oral small-dose IFNα2b group was significantly higher than that in the placebo control group, and the difference was statistically significant (P<0.05). The fever fading time, vomiting and diarrhea disappeared time of children in the oral large-dose and small-dose IFNα2b groups were significantly shorter than the placebo control group (P<0.05). In addition, the oral large-dose IFNα2b group was significantly shorter than the oral small-dose ones (P>0.05) in terms of fever fading time, diarrhea disappearing time and vomiting disappearing time (P>0.05). The loss rate of stool rotavirus antigen of the 3rd in the oral large-dose rhIFNα2b group was 43.3%, significantly higher than 13.3% of oral small-dose IFNα2b group and 6.7% of the placebo-control group. However, there was no significant difference in the loss rate of stool rotavirus antigen of the 5d between the three groups (P>0.05). No any adverse drug reactions were found during the study. Conclusion: The therapeutic effect of oral IFNα2b on pediatric patients with rotavirus enteritis is encouraging, which is worthy of further clinical exploration and application, and its therapeutic effect has certain dose-correlation.

Key words: enteritis rotavirus interferon α2b oral route different dose children

电话：023-63626877；023-63633143 传真： Email：ekyxzz@cqmu.edu.cn