A comparison of four different treatment regimens as the first-line treatment of Helicobacter pylori in Chinese children and investigation of resistance -a multicenter study

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With the resistance of Helicobacter pylori increasing, low and unsatisfactory eradication rate (64%) have been observed with standard triple therapy in European children. Which regimen is appropriate for Chinese children? There is no large scale, multi center studies in China about treatment, CYP2C19 gene polymorphism, resistance rate and resistance genotype. We want to perform a research to compare three different treatment regimens（triple therapy, sequential therapy, bismuth quadruple therapy and concomitant therapy）as the first-line treatment of Helicobacter pylori in Chinese children and investigation of resistance and impact factors. The results of the study will provide theoretical basis to make the new guideline of diagnosis and therapy of Helicobacter pylori in Chinese children. It advance instruct and norm the clinical practice for Chinese pediatrian.to increase the cure rate of Helicobacter pylori and decrease the resistance. To identify factors that influence efficacy of the regimens.

This is a prospective, multicenter,open-label, randomized controlled trial.Based upon published data, we assumed that Hp eradication rate would be 67.7% with standard therapy, 81.4% with sequential therapy, 91.9% with bismuth quadruple therapy and 91.2% with concomitant therapy. Based on a statistical power of 0.9 to detect a significant difference($P<0.05$), 69 patients were required for each group in one center. In consideration of up to 15% subject loss of follow-up, at least 1440 patients total were required.

Inclusion Criteria:

Children 6-18 years of age who were referred for upper endoscopy and confirmed to have Hp infection

Exclusion Criteria:

Patients were excluded if they had taken proton pump inhibitors, H2-receptor antagonists or antibiotics in the 4 weeks prior to the study. Patients with known antibiotic allergy,hepatic impairment or kidney failure were also excluded. Patients who received Hp therapy before were also excluded.

Eligible children were randomly divided into four groups: standard triple therapy, sequential therapy, bismuth quadruple therapy and concomitant therapy. The course of

treatment is 14 days. The primary outcome measure was the Hp eradication rate at 4-6 weeks after completion of treatment which was confirmed by a negative of 13 UBT. Secondary outcome measures included side effects, impact factor and changes of microbiome after the therapy.