INPLASY PROTOCOL

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Corresponding author:
Hua Zeng

2945487001@qq.com

Author Affiliation:
shenzhen university

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Conflicts of interest:
None.

Entecavir in the treatment of chronic hepatitis B in children and adolescents: Systematic review and meta-analysis

Zeng, H[1]; Liu, Y[2].

Review question / Objective: **Participant: children and adolescents<20 years old with hepatitis b, whose diagnosis met the diagnostic criteria of the guidelines for the prevention and treatment of chronic hepatitis b (2019 edition). Intervention:the intervention group (the experimental group) was treated with entecavir. control : the control group was treated with non-exposed. outcome indicators: serum hbv-dna negative conversion rate, serum HBeAg negative conversion rate, serum anti-hbe positive conversion rate, serum HBsAg clearance rate, serum ALT renormalization rate, YMDD mutation rate, adverse reaction rate, etc. Study type: randomized controlled trial (RCTS) and observational studies.**
Condition being studied: **Entecavir is an effective security nucleoside analogues, have been approved for children over the age of 2, its good antiviral effect, high safety and high genetic barrier to resistance and low resistant (or) makes it the optimization of pediatric patients and adolescents with chronic hepatitis b, in order to comprehensively evaluate the current treatment of entecavir in children and adolescents with hepatitis b, Systematic review the meta-analysis is essential to make.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 May 2020 and was last updated on 30 May 2020 (registration number INPLASY202050112).

INTRODUCTION

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METHODS

Participant or population: Children and adolescents<20 years old with hepatitis b, whose diagnosis met the diagnostic criteria of the guidelines for the prevention and treatment of chronic hepatitis b (2019 edition).

Intervention: The intervention group (the experimental group) was treated with entecavir.

Comparator: Control group was treated with non-exposed.

Study designs to be included: randomized controlled trial (RCTS) and observational studies.

Eligibility criteria: We included studies that enrolled children and adolescents(<20 years) with chronic HBV infection treated with entecavir.

Information sources: We search from PubMed, Embase, the Cochrane Library, CBM, CNKI, VIP, Wanfang database.If the data cannot be extracted, we will contact the author to obtain the original data.

Main outcome(s): ALT normalization, HBV DNA suppression, HBeAg/HBsAg seroconversion, and HBeAg/HBsAg loss, growth of height and weight, cirrhosis, decompensated liver disease and HCC.

Quality assessment / Risk of bias analysis: Two reviewers independently assessed the risk of bias using the Cochrane risk of bias tool and the Newcastle-Ottawa Scale for RCTs and observational studies. Quality of evidence was evaluated using the Grading of Recommendations Assessment, Development, and Evaluation approach. Criteria used to evaluate quality of evidence were risk of bias, indirectness , imprecision, inconsistency and publication bias.

Strategy of data synthesis: For dichotomized outcomes, we calculated risk ratios (RRs) and 95% confidence intervals (CIs) using binomial distribution. We then pooled the log-transformed RRs using the DerSimonian and Laird random-effect method with the heterogeneity estimated from the Mantel-Haenszel model. To measure the overall heterogeneity across the included studies, we calculated the I^2 statistic, with I^2 >50% suggesting high heterogeneity. All statistical analyses were conducted using Revman, version 5.3. We explored the impact of publication bias using the Egger regression asymmetry test and by constructing funnel plots if a sufficient number of studies (>20) per outcome was available and heterogeneity was low.

Subgroup analysis: Time:treatment last for within one year or more than one year. dose: entecavir treated with 0.5mg/d or other dosage. initial treatment or retreatment.

Sensibility analysis: Time: treatment last for within one year or more than one year. Dose: entecavir treated with 0.5mg/d or other dosage. Initial treatment or retreatment.

Keywords: entecavir; children; adolescent; hepatitis b.

Contributions of each author:
Author 1 - Hua Zeng - Author 1 drafted the manuscript
Author 2 - Yuanliang Liu - The author provided statistical expertise.