INPLASY PROTOCOL

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None declared.

Ursodeoxycholic acid in the treatment of neonatal jaundice: a systematic review and meta-analysis

Gao, X[1]; Kong, X[2]; Xiang, J[3].

Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of for ursodeoxycholic acid on neonatal hyperbilirubinemia.**
Condition being studied: **Neonatal hyperbilirubinemia is one of the most common diseases that requires medical attention and hospitalization.The clinical intervention on neonatal hyperbilirubinemia include phototherapy, exchange transfusion and phenobarbitone. But, they all have some complications. Ursodeoxycholic acid (UDCA) has been widely used in the treatment of cholestatic hepatic diseases, gallstones and so on. And it is very safe in the treatment of direct hyperbilirubinemia in infants. There are some studies about the effect of UDCA in lowering neonatal hyperbilirubinemia, but no systematic reviews on this topic. So we conduct this systematic review to evaluate the effect of UDCA in neonatal hyperbilirubinemia.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 February 2021 and was last updated on 07 February 2021 (registration number INPLASY202120027).

INTRODUCTION

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METHODS

Participant or population: Inclusion criteria: age28days, unconjugated hyperbilirubinemia.

Intervention: Ursodeoxycholic acid oral solution was used in combination with routine therapy, such as phototherapy, albumin injuction or immune globulin injection.

Comparator: The control group use the routine therapy without ursodeoxycholic acid.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: RCTs, intervention groups oral ursodeoxycholic acid, control groups use placebo.

Information sources: We will search, with no time restrictions, the following databases for relevant English language literature: PubMed (MEDLINE), the Cochrane Central Register of Controlled Trials (CENTRAL) and Web of Science.The search string will be built as follows: (hyperbilirubin OR Direct bilirubin OR Kernicterus) AND (newborn OR neonatal OR infant) AND (Ursodeoxycholic acid OR UDCA). The electronic database search will be supplemented by a manual search of the reference lists of included articles.

Main outcome(s): Duration of phototherapy, bilirubin level, length of hospital stay and reduction rate of bilirubin.

Quality assessment / Risk of bias analysis: Cochrane risk of bias tool was used to assess the methodological quality of included RCTs.We assessed the quality of every article on six elements:selection bias(random sequence generation and allocation concealment), performance bias, detection bias, reporting bias and other bias

Strategy of data synthesis: The Cochrane Review Manager 5.4 was performed for the meta-analysis. Risk rate was calculated for dichotomous outcome(eg. efficacy rate). The inconsistency index statistic I^2 for heterogeneity was conducted. If I^2 >50% or $p<0.05$, a random effect model was used. If there was no heterogeneity, the fixed effect model will be chosen.

Subgroup analysis: None.

Sensitivity analysis: The article was removed one at a time, and meta-analysis was conducted again, compare the new outcomes with the previse outcomes before article be excluded. If there was no significant difference between the 2 results, it demonstrates that the sensitivity was low, and the results were credible. Otherwise, it demonstrates that the sensitivity was high, and the outcomes were not stable.

Country(ies) involved: China.

Keywords: neonatal hyperbilirubinemia, ursodeoxycholic acid.

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