INPLASY PROTOCOL

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Corresponding author:
Feifei Shen

SFF0386575786@126.com

Author Affiliation:
Luoyang Polytechnic

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Conflicts of interest:
None.

Value of Anti-HBV in Serum Tested by ELISA3 in diagnos of Hepatitis B: a protocol for systemic review and meta analysis

Shen, F[1]; Ren, X[2]; Liu, H[3]; Zhang, H[4].

Review question / Objective: **To systematically review the diagnostic value of anti-HBV in serum tested by the ELISA in patients with hepatitis B.**
Condition being studied: **Hepatitis B virus (HBV) infection is A global public health problem. There are about 400 million chronically infected people, nearly One-third of people have been infected with HBV, especially in developing countries. China is a high-risk area of viral hepatitis, especially hepatitis B virus Inflammation, not only the population infection rate is high, but also easy to turn into chronic hepatitis, some Cases can evolve into liver cirrhosis or even primary liver cancer. therefore, Early diagnosis and early treatment of hepatitis B patients is particularly important want. The ELISA method is simple to operate, the results are easy to judge, the price is low, no special equipment and high standard experimental conditions are needed, and it is easy to popularize and apply. In order to evaluate the value of ELISA reagents in the diagnosis of HBV, this study will comprehensively collect relevant literature for Meta analysis, in order to provide more reliable evidence for the clinic.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 October 2020 and was last updated on 24 November 2020 (registration number INPLASY2020100051).

INTRODUCTION

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METHODS

Participant or population: HBV patients.

Intervention: None.

Comparator: Non-hepatitis B controls (healthy Volunteers, blood donors, hemodialysis patients, HIV-infected people, etc.).

Study designs to be included: ELISA reagents have been published at home and abroad to diagnose HBV.

Eligibility criteria: ¢Ù Literature that does not describe specific diagnostic criteria and has not been confirmed by the gold standard; ¢Ú Literature that cannot be used with incomplete data; ¢Û Literature that is repeatedly published and reported.

Information sources: PubMed, EMbase, Th e Cochrane Library, CBM, CNKI, VIP, WanFang Data.

Main outcome(s): sensitivity£¬Sen£» specifi city£¬Spe£» positive likelihood ratio£¬+LR£» negative likelihood ratio£¬šCLR£» diagnostic odds ratio£¬DOR.

Quality assessment / Risk of bias analysis: Two or more independent reviews will appraise the quality of the included trials using the risk of bias tool developed by the Cochrane Collaboration.We will appraise each study in terms of selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), selective reporting bias and other bias. Trials will be evaluated and classified into three levels: low risk, high risk and unclear. Any disagreements will be arbitrated by a third reviewer. The Grading of Recommendations Assessment, Development and Evaluation System (GRADE) system will be used to grade the quality of the evidence for main outcomes.Two reviewers will use the GRADE system to independently assess the quality of evidence for each outcome. Evidence quality will be rated ¡®high¡¯, ¡®moderate¡¯, ¡®low¡¯ or ¡®very low¡¯ according to the GRADE rating standards. The quality of evidence of a specific study will be assessed according to the risk of bias, inconsistency, indirectness, imprecision and publication bias.

Strategy of data synthesis: Two researchers will independently extract data. The extracted data will include author, year of publication, study design, type of surgery, sample size (of each group), baseline characteristic differences between the treatment and control groups, intervention of the treatment and control groups, outcomes, results, and conclusions. Any discrepancies and doubts will be clarified with the help of a third researcher. The extracted data will be presented in a summary table.

Subgroup analysis: If the included studies show high heterogeneity and the number of included trials is sufficient, subgroups will be made based on the type of control group.

Sensibility analysis: Sensitivity analysis will be carried out to evaluate the robustness of the meta-analysis by repeating the meta-analysis when it includes a vague or arbitrary decision making process.

Country(ies) involved: China.

Keywords: Hepatitis B; Enzyme-linked immunosorbent assay (ELISA); Meta-analysis.

Contributions of each author:
Author 1 - Feifei Shen - develop the study protocol and will implement the systematic review.
Author 2 - Xiaodan Ren - provide the statistical analysis plan of the study and will conduct data analysis.
Author 3 - Haiqiang Liu - perform the study search, screening and extraction of data.
Author 4 - Hewei Zhang - wrote the first manuscript draft and gave input to the final draft of the protocol.