

INPLASY PROTOCOL

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None declared.

Diagnostic efficacy of serum Krebs von den Lungen-6 for Dermatomyositis/ Polymyositis-associated interstitial lung diseases: A protocol for meta-analysis

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Review question / Objective: To investigate the diagnostic value of Krebs von den Lungen-6(KL-6) in dermatomyositis/polymyositis(DM /PM)-associated interstitial lung diseases(ILD).

Condition being studied: KL-6 is a high molecular mucin like glycoprotein mainly expressed in type II alveolar cells and bronchial epithelial cells, and is significantly elevated in serum and alveolar lavage fluid when cells are injured, effectively reflecting lung injury. Studies have shown that KL-6 can be an effective indicator for the diagnosis of DM / pm-ild, but a systematic review / meta-analysis focusing on patients with DM / pm-ild is not available at this time. This study comprehensively evaluated the diagnostic value of KL-6 for patients with DM / pm-ild and expected to provide an evidence-based reference for relevant clinical decision-making.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 June 2022 and was last updated on 27 June 2022 (registration number INPLASY202260106).

INTRODUCTION

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METHODS

Search strategy: Pubmed database, The Cochrane Library, Web of Science, China National Knowledge Infrastructure, Wangfang database, the Chongqing VIP Chinese Science. will be searched from database establishment to Dec 31st, 2022.

Participant or population: Patients with dermatomyositis/polymyositis will be included. Our review included studies using KL-6. There will be no restrictions in terms of the patients age, gender, race, education or economic status.

Intervention: All treatments containing KL-6.

Comparator: Do not make restrictions.

Study designs to be included: Intervention studies or observational studies.

Eligibility criteria: Inclusion and exclusion criteria are categorized by population, interventions, comparators, outcomes and study design (PICOS). The year of publication is restricted from database establishment to 2022 and there were no restrictions regarding the language of the article.

Information sources: Web of Science, PubMed and The Cochrane Library will be been comprehensive searched. Given that KL-6 is widely used in China, we will search the following Chinese databases: China

National Knowledge Infrastructure, the Chongqing VIP Chinese Science and Wanfang Data from database establishment to 2022. The search strategy for PubMed is as follows. And the equivalent search words will be used in other databases as well.

Main outcome(s): Sensitivity, specificity.

Additional outcome(s): Mean KL-6 levels.

Data management: Two review authors will independently extract data on methods, patients, interventions, outcomes and results from the included studies, using a preformulated data collection form.

Quality assessment / Risk of bias analysis: The corresponding assessment tools were used according to the types of included studies. Disagreements will be resolved by discussion or by involving another reviewer.

Strategy of data synthesis: The stata15.0 software was used for meta-analysis, and the quantitative data were quantified using weighted mean difference (WMD) with its 95% confidence interval (CI) as the corresponding effect size, and the diagnostic experimental indexes were pooled and analyzed using sensitivity (SEN), specificity (SPE), diagnostic odds ratio (DOR) with its 95% confidence interval. Between study heterogeneity was determined according to I². Fixed effects model was selected for meta-analysis if I² < 50% deemed the between study heterogeneity acceptable; Random effects model was used for pooling if P < 0.1, I² > 50% considered large between study heterogeneity; The Spearman correlation coefficient between sensitivity and FP rate was calculated, and a large threshold effect was considered when the correlation coefficient was > 0.6. Sources of heterogeneity were sought by subgroup analysis or meta regression, and publication bias was evaluated by Begg's test versus deek's test, and the stability of the results was judged according to sensitivity analysis. The summary receptor operating characteristic curve (SROC) was plotted, and the area under the curve (AUC)

was calculated, the closer the AUC was to 1 indicated the greater the diagnostic value of the diagnostic test. The stata15.0 software was used for meta-analysis, and the quantitative data were quantified using weighted mean difference (WMD) with its 95% confidence interval (CI) as the corresponding effect size, and the diagnostic experimental indexes were pooled and analyzed using sensitivity (SEN), specificity (SPE), diagnostic odds ratio (DOR) with its 95% confidence interval. Between study heterogeneity was determined according to I². Fixed effects model was selected for meta-analysis if I² < 50% deemed the between study heterogeneity acceptable; Random effects model was used for pooling if P < 0.1, I² > 50% considered large between study heterogeneity; The Spearman correlation coefficient between sensitivity and FP rate was calculated, and a large threshold effect was considered when the correlation coefficient was > 0.6. Sources of heterogeneity were sought by subgroup analysis or meta regression, and publication bias was evaluated by Begg's test versus deek's test, and the stability of the results was judged according to sensitivity analysis. The summary receptor operating characteristic curve (SROC) was plotted, and the area under the curve (AUC) was calculated, the closer the AUC was to 1 indicated the greater the diagnostic value of the diagnostic test.

Subgroup analysis: A priori defined subgroup analyses by Years of publication, type of literature, language of publication, type of study, and KL-6 testing methods.

Sensitivity analysis: Sensitivity analyses will be conducted to examine the overall effect size of the primary outcome measurement while temporarily removing: (1) each study individually from the meta-analysis, (2) studies with sample sizes ≤20 across conditions, (3) studies with attrition rates ≥30% in at least one trial arm, and (4) studies in each rating category of overall risk of bias (ie, high- moderate respectively low risk of bias).

Country(ies) involved: China.

Keywords: Dermatomyositis, polymyositis, KL-6, Krebs von den Lungen-6, meta-analysis, systematic review, protocol.

Dissemination plans: The results of this study will be published in peer-reviewed journals.

Contributions of each author:

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Author 3 - Yang, LH.

Author 4 - Yi, W.

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