Myocarditis following mRNA Covid-19 vaccination: a pooled analysis

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ABSTRACT

Vaccination against SARS-CoV-2 has emerged as the main tool to confront the Covid-19 pandemic. However, concerns were raised about potential adverse effects of mRNA vaccines, especially the development of myocarditis. The present study aims to gather current evidence and assess the clinical charactertistis of myocarditis cases, describe their clinical course and identify factors predisposing for critical illness.

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1 Objective To gather current evidence regarding the occurrence of myocarditis associated with vaccination against SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2) with mRNA vaccines.

2 Study design Systematic review and pooled analysis using individual participant data

3 Data sources Medline, Scopus, Web of Science and CENTRAL will be systematically searched from inception. Google Scholar will be searched to provide grey literature coverage. The reference lists of the included studies will be also screened to identify possible missing articles (snowball method).

4 Eligibility criteria The population of the study will consist of adult patients diagnosed with myocarditis following vaccination with mRNA Covid-19 vaccines (BNT162b2 or mRNA-1273). Outcomes of interest include

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electrocardiographic changes, development of heart failure, cardiac magnetic resonance findings, admission to the intensive care unit and death. Case reports and case series reporting individual participant data will be included. Cohort studies will be also included, requesting individual patient data from the authors of original articles. Patients vaccinated with non-mRNA vaccines, those with age <18 years or patients with pericarditis without myocardial involvement will be excluded.

5 Quality assessment Quality assessment was performed by evaluating the risk of bias of individual studies in the following domains: selection, ascertainment, causality and reporting. The risk of bias will be evaluated as low, unclear or high.

6 Data extraction The following data will be extracted: number of cases, sex, age, vaccine type, days from vaccination, vaccine dose, cardiovascular comorbidities, history of Covid-19, clinical presentation with chest pain, anti-spike SARS-CoV-2 antibodies, electrocardiographic findings, presence of heart failure, ejection fraction, magnetic resonance findings, treatment, symptom resolution, length of hospital stay, admission to intensive care unit and death.

7 Data analysis The individual participant data coming from case reports/series will be combined, creating the pooled cohort. The p-value threshold of 0.05 will be used to define statistical significance. Normally distributed data will be expressed as mean and standard deviation and will be compared using the Student's t-test. Otherwise, the median and interquartile range (IQR) will be reported and comparisons will be performed with the Mann-Whitney U-test. Categorical variables will be compared with the chi-squared test or the Fischer's exact test. Logistic regression analysis will be conducted to evaluate factors associated with critical illness. In case of the presence of cohort studies without available individual participant data, these will be statistically combined with the pooled cohort using proportion meta-analysis. Random-effects (DerSimonian-Laird) models will be fitted and inter-study heterogeneity will be quantified by calculating the inconsistency index.

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