

INPLASY PROTOCOL

To cite: Dong et al. Incidences of Adverse Reactions in BNT162b2: A Meta-analysis. Inplasy protocol 202210043. doi: 10.37766/inplasy2022.1.0043

Incidences of Adverse Reactions in BNT162b2: A Meta-analysis

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Received: 09 January 2022

Published: 09 January 2022

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Support: There is no support.

Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest:
None declared.

Review question / Objective: This study searched PubMed, Cochrane Library, Web of Science, Embase Electronics, and other databases to collect healthy adults aged 16 and older, subjects with no previous history of COVID-19 infection, A randomized controlled trial of Pfizer's vaccine BNT162b2 versus placebo. Using RevMan5.4 software, meta-analysis was conducted to compare the effects of injection of BNT162b2 and placebo on the incidence of adverse reactions in healthy adults over 16 years of age. Main indexes include total incidence of adverse reactions, the incidence of local adverse reactions at the injection site (including red hot accessories), the incidence of systemic adverse reactions, including fever, headache, rash, urticaria, joint pain, muscle pain, gastrointestinal tract reaction, fatigue, cough, etc.), death rate, so as to provide a reference for clinical practice.

Information sources: The following electronic databases will be searched from January 2020 to November 2021: PubMed, the Cochrane Library, Web of Science, Embase Electronics. In addition, reference lists of the included studies were manually searched to identify additional relevant studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 January 2022 and was last updated on 09 January 2022 (registration number INPLASY202210043).

INTRODUCTION

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Condition being studied: COVID-19, caused by severe acute respiratory syndrome Type 2 coronavirus (SARS-COV-2), was first reported in China on 31 December 2019. This is the most extensive global pandemic to hit humanity in nearly a century, posing a serious crisis and a severe test for the world. Human life, safety, and health are seriously threatened. Vaccines are considered to be the most effective means of controlling Novel coronavirus infection due to the lack of effective antiviral drugs and the persistence of root control of the outbreak. At present, countries around the world are urgently developing COVID-19 vaccines, mainly including the following six technical routes: inactivated vaccine, attenuated live vaccine, protein subunit vaccine, viral vector vaccine (replication/non-replication), nucleic acid vaccine (DNA, mRNA), and virus particle like a vaccine. Among them, the BNT162b2 mRNA vaccine developed by Pfizer-BioNTech was authorized by FDA for emergency use in December 2020. Due to its excellent characteristics of mRNA vaccine and high effectiveness in clinical trials, it is widely used in Europe and The United States. Currently, the safety and immunogenicity of BNT162b2 in phase I / II, II and II / III clinical trials have been published, showing efficacy. However, the safety of BNT162b2 remains controversial. Therefore, this study systematically evaluated the safety of BNT162b2, in order to provide a reference for its clinical application.

METHODS

Search strategy: The following electronic databases will be searched from January 2020 to November 2021: PubMed, the Cochrane Library, Web of Science, Embase

Electronics. In addition, reference lists of the included studies were manually searched to identify additional relevant studies. PubMed search queries (COVID-19 OR 2019 Novel Coronavirus disease OR 2019nCoV OR COVID-19) SARS-CoV-2[Title/Abstract]) AND (BNT162b2[Title/Abstract])) AND (side effect[Title/Abstract] OR safety[Title/Abstract] OR adverse reaction[Title/Abstract] OR security[Title/Abstract] OR adverse events[Title/Abstract])). As all the data we collected and synthesized were from previously published studies, the Institutional Review Board concluded that approval and informed consent was not required for this study.

Participant or population: Healthy adults aged ≥ 16 years with no previous history of COVID-19 infection.

Intervention: The intervention of the experimental group was BNT162b2 vaccine.

Comparator: The intervention in the control group was a placebo injection.

Study designs to be included: The study type was a randomized controlled study(RCTs).

Eligibility criteria: We will use PICOS(participants, interventions, outcome indicators, design options) description model to develop eligibility criteria for participants. The inclusion criteria for literature retrieval were as follows :(1) healthy adults aged ≥ 16 years with no previous history of COVID-19 infection; (2) BNT162b2 was used in the experimental group, and placebo or other vaccines were used in the control group; (3) Outcome indicators included the incidence of adverse reactions; (4) Randomized controlled study (RCT) studies. Exclusion criteria are as follows :(1) repeated publication; (2) The literature did not belong to the included research type; (3) Lack of outcome index data; (4) Studies that cannot be analyzed due to lack of full text or incomplete data.

Information sources: The following electronic databases will be searched from January 2020 to November 2021: PubMed, the Cochrane Library, Web of Science, Embase Electronics. In addition, reference lists of the included studies were manually searched to identify additional relevant studies.

Main outcome(s): The total incidence of adverse reactions; Incidence of local adverse reactions at the injection site (including redness, swelling, heat and itching); Incidence of systemic adverse reactions (including fever, headache, rash, urticaria, arthralgia, muscle pain, gastrointestinal reactions, fatigue, cough, etc.); Mortality rate, etc.

Data management: We use NoteExpress to manage papers.

Quality assessment / Risk of bias analysis: Two researchers will assess study quality across seven domains using the Cochrane Risk of Bias Tool. If any different points of view emerge, another experienced researcher will help resolve them through discussion.

Strategy of data synthesis: RevMan 5.4 software will be used for data analysis. The dichotomous data will be expressed as risk ratio (RR) and 95% confidence interval (CI), and the continuous data will be estimated as mean difference (MD) or standard mean difference (SMD) and 95% CI. Statistical heterogeneity of conformity tests was examined by the I^2 test. If in enough eligible studies there is little heterogeneity ($I^2 \leq 50\%$) of the same results, the data are aggregated using a fixed-effects model, and meta-analysis is performed. If there is significant statistical heterogeneity between the included studies ($I^2 > 50\%$), the random-effects model is used to summarize the data and subgroup analysis is used to determine its source. If we cannot examine the source of apparent heterogeneity, we will use descriptive analysis rather than meta-analysis. The results of the meta-analysis will be displayed through the forest map.

Sensitivity and subgroup analyses were performed to explore whether significant heterogeneity existed. Two researchers will assess study quality across seven domains using the Cochrane Risk of Bias Tool. If any different points of view emerge, another experienced researcher will help resolve them through discussion.

Subgroup analysis: We will perform subgroup analysis according to the different details of interventions, study quality and outcome indicators.

Sensitivity analysis: Sensitivity analysis: We will perform sensitivity analysis based on sample size, research design, heterogeneity quality, methodological quality and statistical model, excluding trials with low quality, and ensure the stability of analysis results.

Language: Only English literature was included.

Country(ies) involved: China.

Keywords: COVID-19; 2019 novel coronavirus disease; 2019nCoV; SARS-CoV-2; BNT162b2; side effect; safety; adverse reaction; security; adverse events.

Dissemination plans: We plan to publish this meta-analysis in relevant scientific journals and disseminate it widely on the Internet.

Contributions of each author:

Author 1 - Yi Dong - Drafted the manuscript; Methodology; Software.

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Author 2 - LiJia Liu - Data selection; Data extraction.

Author 3 - Jianing Liu - Data selection; Data extraction.

Author 4 - Tianqi Liao - Quality assessment.

Author 5 - Jieru Zhou - Data curation; Investigation.

Author 6 - Huaian Bu - The author read, provided feedback and approved the final manuscript.

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