INPLASY PROTOCOL

To cite: Li et al. A systematic review and meta-analysis: The impact of corticosteroids on the outcome of fungal disease. Inplasy protocol 202280110. doi: 10.37766/inplasy2022.8.0110

Received: 31 August 2022

Published: 31 August 2022

Corresponding author:
David Denning

david.denning@manchester.co.uk

Author Affiliation:
The University of Manchester.

Support: **None.**

Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
None declared.

A systematic review and meta-analysis: The impact of corticosteroids on the outcome of fungal disease

Li, ZL[1]; Denning, D[2].

Review question / Objective: **How does the treatment with corticosteroids(dose; duration time; with or without) impact the outcome of fungal diseases?**
Condition being studied: **Corticosteroids have a complicated role as a risk factor or a treatment for many fungal diseases. (Aspergillosis, candidiasis, fungal keratitis, hepatosplenic candidiasis, Talaromyces, Histoplasma, Pneumocystis jirovecii, Cryptococcus, coccidioidomycosis). Our systematic review will aim to assess the outcome (survival, vision, and organ transplant loss) of patients with fungal diseases with and without corticosteroid treatment; corticosteroid dose and continuing or not continuing on corticosteroids.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 August 2022 and was last updated on 31 August 2022 (registration number INPLASY202280110).

INTRODUCTION

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METHODS

Search strategy: **A literature search will perform through PubMed; Web of Science;**

Embase and CNKI databases for articles published from inception to June 1st, 2022 in peer-review journals. Studies published in languages other than English and Chinese will exclude if no translated version of the manuscript was available.

Participant or population: Inclusion: 1.Patients of all ages, both sexes and all ethnicities with a documented fungal disease diagnosed using recognised diagnostic criteria.2. Some participants received corticosteroid therapy during the course of their fungal disease and others do not, studied either in randomized, case control or cohort studies. Exclusion: 1. Participants without a fungal disease.2. Participants had other microbial infections (bacterial or parasite).3. Participants have been received corticosteroid therapy before the diagnosis (except patients with Pneumocystis jirovecii pneumonia).

Intervention: 1. Patients with fungal diseases treated with corticosteroids.2. Patients with fungal diseases treated with high corticosteroid doses, related to outcome.

Comparator: 1. Patients with fungal diseases treated without corticosteroids.2. Patients with fungal diseases treated with low corticosteroid doses, related to outcome.

Study designs to be included: RCTs, cohort study, case-control study.

Eligibility criteria: Studies will include that meet the following criteria: (1) original large observational case series or randomized controlled studies; (2) reports of outcome (survival, organ transplant loss or vision) is clearly described; (3) reports with data on the outcome between patients treated with and without corticosteroids (4) the diagnostic criteria for the fungal disease were clearly provided and internationally accepted. We also seek information on corticosteroid dose and duration related to outcome and if available were analysed.The exclusion criteria will as follows: (1) no information on the patient outcome; (2) outcome not related to therapy of corticosteroid; (3) in vitro and experimental animal studies; (4) reports of single case experiences or small series.

Information sources: 1.A comprehensive literature search was performed through PubMed; Web of Science; Embase and CNKI databases 2.We will perform a search manually for other review (either systematic or narrative).

Main outcome(s): The primary outcomes assessed were mortality and outcome of vision among fungal disease patients 1) with and without corticosteroid treatment. 2) high or low corticosteroid dose, related to outcome. (if available) 3) patients continuing or not continuing on corticosteroids. (if available).

Quality assessment / Risk of bias analysis: Two researchers will perform quality assessments using the Newcastle-Ottawa Scale (NOS) for cohort and case-control studies; using version 2 of the Cochrane risk-of-Bias tool for Randomized controlled trials (RCTs).

Strategy of data synthesis: We will perform a meta-analysis of RCTs and cohort and case-control studies separately respectively. The software of Revman 15 will use for RCTs while the STATA17 will use for cohort studies. Additionally, if RR and OR were not shown in the original paper, we will calculate them using the original data extracted from each paper. For RCTs, we will use the data of events and the total patients' numbers in both treatment and control groups. For cohort studies and case-control studies, we will combine the OR and HR in STATA to perform a meta-analysis given that these cohorts recruited groups of patients with a similar risk for death, a single episode of infection and most deaths occurred within 30-45 days. We will also calculate 95% confidence intervals (CIs) in STATA. Data are displayed using forest plots, and the test of the overall effect, P value, and RR reflects the results.

Subgroup analysis: Subgroup analyses will perform based on the dose of corticosteroid in aspergillosis and disease types in candidiasis.

Sensitivity analysis: None.

Country(ies) involved: United Kingdom, China.

Keywords: fungal disease; corticosteroids; survival; mortality; vision change.

Contributions of each author:
Author 1 - Zhaolun Li.
Email: zhaolun.li@student.manchester.ac.uk
Author 2 - David Denning.