INPLASY PROTOCOL

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Corresponding author:
Tai-Li Chen

102311116@gms.tcu.edu.tw

Author Affiliation:
Department of Medical Administration, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Hualien, Taiwan

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
The authors declare no conflict of interest.

Efficacy and safety of adalimumab in hidradenitis suppurativa management: A systematic review and meta-analysis of randomized controlled trials with trial sequential analysis

Lu, JW[1]; Chen, TL[2].

Review question / Objective: **To evaluate the efficacy and safety of adalimumab for patients with hidradenitis suppurativa.**
Condition being studied: **Adalimumab is the first-line biologic agent in the management of moderate-to-severe hidradenitis suppurativa (HS), after failure of conventional treatments, but the evidence is lacking.**
Information sources: **PubMed, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) Current Controlled Trials, ClinicalTrials.gov, and http://www.centerwatch.com will be search for any unpublished or ongoing trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 August 2020 and was last updated on 31 August 2020 (registration number INPLASY202080127).

INTRODUCTION

Review question / Objective: **To evaluate the efficacy and safety of adalimumab for patients with hidradenitis suppurativa.**

Condition being studied: **Adalimumab is the first-line biologic agent in the management of moderate-to-severe hidradenitis suppurativa (HS), after failure of conventional treatments, but the evidence is lacking.**

METHODS

Participant or population: patients with moderate-to-severe hidradenitis suppurativa.

Intervention: Subcutaneous adalimumab.

Comparator: Placebo.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Randomized controlled trials compared the efficacy and safety of adalimumab with that of a placebo for the treatment of moderate-to-severe HS.

Information sources: PubMed, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) Current Controlled Trials, ClinicalTrials.gov, and http://www.centerwatch.com will be search for any unpublished or ongoing trials.

Main outcome(s): Efficacy outcomes: patients achieving clinical response, change from baseline of modified Sartorius score, and change from baseline of Dermatology Life Quality Index (DLQI); Safety outcomes: serious adverse events, infectious adverse events, headache, and nasopharyngitis.

Quality assessment / Risk of bias analysis: The revised Cochrane risk of bias (RoB 2.0) tool will be use as a methodological quality appraisal.

Strategy of data synthesis: The estimated rate ratio or risk ratio (RR) will be calculated with 95% confidence interval (CI) for dichotomous outcomes, while standardized mean difference (SMD) will be calculated with 95% CI for continuous outcomes.

Subgroup analysis: We will conduct a predefined subgroup analysis of adalimumab given weekly and that given every other week to separate the different methods of administration.

Sensibility analysis: None.

Country(ies) involved: Taiwan.

Keywords: Adalimumab, Hidradenitis suppurativa, Acne inversa.

Contributions of each author:
Author 1 - Jing-Wun Lu - literature search, data extraction, quality appraisal.
Author 2 - Tai-Li Chen - literature search, data extraction, quality appraisal, and manuscript writing.