

INPLASY PROTOCOL

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The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The Effectiveness and Safety of Iguratimod in Primary Sjögren's Syndrome: A Systematic Review and Meta-Analysis

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Review question / Objective: P: primary Sjögren's Syndrome patients; I: iguratimod; C: iguratimod/non-iguratimod; O: salivary flow rate, Schirmer's test, erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), immunoglobulin G (IgG), Platelets (PLT), EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI), EULAR Sjogren's Syndrome Patient Reported Index (ESSPRI), effective rate and adverse events (AEs); S: Randomized Controlled Trial (RCT).

Condition being studied: Sjögren's syndrome (SS) is a chronic autoimmune disease characterized by the glandular dysfunction caused by lymphocytic infiltration in exocrine glands and following dry eyes and mouth. Generally, SS can be divided into primary Sjögren's syndrome (pSS) and secondary Sjögren's syndrome (sSS). Other accompanying autoimmune diseases, such as systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA), always played a dominant role in disease progression and treatment decisions of sSS, which might lead to difficulty in evaluating the outcomes of treatment for SS. As a result, we only focus on pSS in this study.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 September 2020 and was last updated on 14 September 2020 (registration number INPLASY202090060).

INTRODUCTION

Review question / Objective: P: primary Sjögren's Syndrome patients; I: iguratimod;

C: iguratimod/non-iguratimod; O: salivary flow rate, Schirmer's test, erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), immunoglobulin G (IgG),

Platelets (PLT), EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI), EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI), effective rate and adverse events (AEs); S: Randomized Controlled Trial (RCT).

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METHODS

Search strategy: Sjögren's syndrome (SS) is a chronic autoimmune disease characterized by the glandular dysfunction caused by lymphocytic infiltration in exocrine glands and following dry eyes and mouth. Generally, SS can be divided into primary Sjögren's syndrome (pSS) and secondary Sjögren's syndrome (sSS). Other accompanying autoimmune diseases, such as systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA), always played a dominant role in disease progression and treatment decisions of sSS, which might lead to difficulty in evaluating the outcomes of treatment for SS. As a result, we only focus on pSS in this study.

Participant or population: Primary Sjögren's Syndrome patients.

Intervention: Igaratimod.

Comparator: Igaratimod/non-igaratimod.

Study designs to be included: Randomized Controlled Trial (RCT).

Eligibility criteria: Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA) Statement.

Information sources: We will search eight databases, including PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), EBSCOhost, Wanfang Med Database, China National Knowledge Infrastructure (CNKI), Chinese VIP Information Database and Chinese Biomedical (CBM) Database from their initial date to August 20, 2020. Meanwhile, we will search related researches in the websites of Clinicaltrials and Chinese Clinical Trial Registry to confirm the availability of relevant unpublished studies.

Main outcome(s): Salivary flow rate, Schirmer's test, erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), immunoglobulin G (IgG), Platelets (PLT), EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI), EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI), effective rate and adverse events (AEs).

Quality assessment / Risk of bias analysis: Two authors will use Cochrane risk of bias tool to assess the methodological quality of each included study independently.

Strategy of data synthesis: Forest plots will be used.

Subgroup analysis: These studies might be divided into different groups by the treatment duration or combined treatment.

Sensibility analysis: Changing inclusion criteria (especially for controversial studies), excluding low-quality studies, using different statistical methods/models to analyze the same data.

Country(ies) involved: China.

Keywords: igaratimod, primary Sjögren's Syndrome; effectiveness; safety; meta-analysis.

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