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Qiu, YF<sup>1</sup>; Li, CF<sup>2</sup>; Sheng, SH<sup>3</sup>.**ADMINISTRATIVE INFORMATION****Support** - Science and Technology Research Project of Education Department Jilin Province (JJKH20221046KJ) and Bethune Project of Jilin University (2020B32).**Review Stage at time of this submission** - Data analysis.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2023100047**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 October 2023 and was last updated on 12 October 2023.**INTRODUCTION**

**Review question / Objective** To investigate the influence of stem cell based therapy on the clinical remission and severe adverse events in adult patients with Crohn's disease.

**Rationale** Stem cells have been suggested to benefit for autoimmune disease, while the efficacy and safety of stem cell based therapy for patients with Crohn's disease is mainly suggested on small-scale pilot studies.

**Condition being studied** Crohn's disease is a type of inflammatory bowel disease which causes multiple symptoms. Despite regular treatment, substantial patients with Crohn's disease are medically refractory. Development of novel treatments for these patients are of clinical significance.

**METHODS**

**Search strategy** A combined search strategy will be used for study identification in PubMed, Cochrane Library, and Embase, which included: (1) "stem cell" OR "precursor cell" OR "progenitor cell" OR "stromal cell"; (2) "inflammatory bowel disease" OR "crohn's disease" OR "crohn disease" OR "regional enteritis" OR "ileocolitis" OR "granulomatous colitis" OR "granulomatous enteritis"; and (3) "random" OR "randomised" OR "randomized" OR "randomly" OR "placebo" OR "control". We only considered studies including human subjects. We will also manually searched the references to related reviews and original articles.

**Participant or population** Adult patients with medically refractory Crohn's disease or Crohn's disease related complex fistula.

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**Intervention** Stem cell based therapy.

**Comparator** Placebo or no additional treatment.

**Study designs to be included** Randomized controlled trials.

**Eligibility criteria** Studies published as full-length article in English language in peer-reviewed journals.

**Information sources** PubMed, Cochrane Library, and Embase.

**Main outcome(s)** Clinical remission.

**Additional outcome(s)** Incidence of severe adverse events.

**Data management** Data extraction via predefined Excel forms. Data extraction will be performed by two independent authors.

**Quality assessment / Risk of bias analysis** The Cochrane Risk of BiasTool will be used to evaluate the quality of the included RCTs.

**Strategy of data synthesis** A random-effects model will be applied to pool the data, by incorporating the possible between-study heterogeneity.

**Subgroup analysis** Predefined subgroup analysis according to study design, patient diagnosis, type and source of stem cells, and follow-up duration will be performed.

**Sensitivity analysis** Sensitivity analysis by excluding dataset one at a time will be performed.

**Language restriction** English.

**Country(ies) involved** China/China-Japan Union Hospital of Jilin University.

**Keywords** Crohn's disease; Stem cell therapy; Meta-analysis.

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