

INPLASY PROTOCOL

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Conflicts of interest:
None.

The Safety and Efficacy of Intralesional Triamcinolone Acetonide for Keloids and Hypertrophic Scars: A Systematic Review and Meta-analysis

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ABSTRACT

Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of intralesional triamcinolone acetonide for keloids and hypertrophic scars.

Search strategy: We will search, with no time restrictions, the following databases for relevant English language literature: PubMed, EMBASE and Cochrane Library. We use the search terms: keloid, cicatrix, hypertrophic, scar, triamcinolone, corticosteroids, steroids. The electronic database search will be supplemented by a manual search of the reference lists of included articles.

Data management: Two authors will independently extract data. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author. The following data will be extracted: author, year of publication, country where the study was conducted, study period, original inclusion criteria, total number of people included in the study, doses of triamcinolone acetonide and time of application, and the size of the scar, et.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 March 2020 and was last updated on 30 March 2020 (registration number INPLASY202030011).

INTRODUCTION

Objectives / Review question: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of intralesional triamcinolone

acetonide for keloids and hypertrophic scars.

Condition being studied: Pathological scars, such as keloids and hypertrophic scars, readily cause physical and

psychological problems. The occurrence of keloids and hypertrophic scars has equal sex distribution and the highest incidence in the second to third decade. They are quite common among people with hereditary factors and those who sustain large-wound surgical procedures, burns and injuries occurring in unsanitary environments. Many methods are clinically available for the treatment of these two types of pathological scars, such as intralesional corticosteroid injections, cryotherapy, radiotherapy, pressure therapy and laser therapy. However, the results and recurrence rates are not satisfactory. Currently, comprehensive surgical treatment is advocated. However, surgery is invasive and is associated with a high recurrence rate. Corticosteroids, particularly the intralesional injection of triamcinolone acetonide (TAC), is the most prevalent treatment method, and has been used since 1961. Sometimes, adverse glucocorticoid reactions following the intralesional injection of large doses of TAC alone occur, such as hypopigmentation, tissue atrophy and terminal arterial dilatation.

METHODS

Participant or population: Patients of both genders with healed full-thickness wounds, newly healed wounds and established scarring with no history of treatment.

Intervention: The intralesional injection of triamcinolone acetonide.

Comparator: The placebo, 5-fluorouracil, bleomycin, Verapamil, et.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Articles will be included if they are independent original RCTs.

Information sources: We will build search strategy sample for Pubmed, and we will adapt similar search strategies for other databases. Other resources We will check and obtain potential studies from clinical trial registry.

Main outcome(s): The primary measure was change in scar (length, volume, height, width, vascularity, pliability, and pigmentation, et). overall scar improvement obtained from patient self-assessment and observer assessment.

Additional outcome(s): The secondary outcome was improvement in erythema, pain, and itch. Adverse events included hypopigmentation, telangiectasia, and skin atrophy, et.

Data management: Two authors will independently extract data. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author. The following data will be extracted: author, year of publication, country where the study was conducted, study period, original inclusion criteria, total number of people included in the study, doses of triamcinolone acetonide and time of application, and the size of the scar, et.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories: Low risk of bias, unclear bias and high risk of bias. The following characteristics will be evaluated: Random sequence generation (selection Bias) Allocation concealment (selection bias) Blinding of participants and personnel (performance bias) Incomplete outcome data (attrition bias) Selective reporting (reporting bias) Other biases Results from these questions will be graphed and assessed using Review Manager 5.3.

Strategy of data synthesis: Risk ratio (RR) for both fixed and random effects models (weighting by inverse of variance) will be used. A continuity correction will also be used for cells with zero values. Between-study heterogeneity will be assessed using the τ^2 , χ^2 (Cochran Q) and I^2 statistics. According to the Cochrane handbook, the I^2 will be considered non-important (60%). Results will be assessed using forest plots

and presented as RRs for the main outcome and secondary outcomes. An influence analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies. Publication bias will be assessed by a funnel plot for meta-analysis and quantified by the Egger method. Statistical analysis will be conducted using Review Manager software for Mac.

Subgroup analysis: We will consider subgroups such as jurisdiction, and race, et.

Sensibility analysis: Whenever necessary, we will examine the stability of study results by eliminating low quality studies.

Language: Only English articles will be involved.

Countries involved: China.

Keywords: keloid, hypertrophic scar, triamcinolone, efficacy, safety.

Contributions of each author:

Author 1 - Conceived the idea for this systematic review. Developed the methodology for the systematic review protocol. Developed the search strategy and will screen potential studies, perform duplicate independent data extraction, risk of bias assessment, GRADE assessment, and data synthesis. Is the guarantor of the review.

Author 2 - Selection of studies and data extraction, writing of the project. search strategy, analysis of results.

Author 3 - Selection of studies and data extraction, writing of the project.