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REVIEW PROTOCOL

Effects of Adalimumab, Clindamycin, and/or Rifampicin in the Treatment of Hidradenitis Suppurativa: A Systematic Review Protocol

Efeitos do Adalimumabe, Clindamicina e/ou Rifampicina no Tratamento da Hidradenite Supurativa: Um Protocolo de Revisão Sistemática

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ABSTRACT

Objective: To evaluate the efficacy, safety, pain, and quality of life associated with the use of adalimumab, clindamycin, and/or rifampicin in the treatment of hidradenitis suppurativa. **Methods:** Prospective and retrospective cohort studies randomized clinical trials and equivalence studies, and economic analyses, conducted in adults diagnosed with hidradenitis suppurativa who have used at least one of the following therapeutic alternatives: adalimumab, clindamycin, or rifampicin, will be included. Studies should address one or more outcomes such as abscess and/or nodule counts, presence of inflammatory nodules, pain levels, quality of life, safety, and cost. Databases consulted will include Medical Literature Analysis and Retrieval System Online (MEDLINE, OVID interface), Excerpta Medica DataBASE (EMBASE), Latin American and Caribbean Literature in Health Sciences (LILACS), Cumulative Index to Nursing and Allied Health Literature (CINAHL, EBSCO interface), Psychological Abstracts (PsycINFO, EBSCO interface), Web of Science (WoS), and Source-Neutral Abstract and Citation Database (Scopus). Screening, selection, and extraction processes will be conducted by independent and previously trained researchers. The risk of bias will be assessed using the Risk of Bias 2.0 and ROBINS-I tools. Results will be summarized in a qualitative and quantitative synthesis, including specificity and subgroup analyses.

Keywords: Hidradenitis suppurativa; Dermatopathies; Adalimumab; Clindamycin; Rifampin; Treatment failure.

RESUMO

Objetivo: Avaliar a efetividade, segurança, níveis de dor e qualidade de vida associados ao uso de adalimumabe, clindamicina e/ou rifampicina no tratamento da hidradenite supurativa. **Método:** Serão incluídos estudos do tipo coorte prospectiva e retrospectiva, ensaios clínicos randomizados e de equivalência, bem como análises econômicas realizadas com adultos diagnosticados com hidradenite supurativa, que tenham utilizado pelo menos uma das seguintes alternativas terapêuticas: adalimumabe, clindamicina ou rifampicina. Os estudos devem abordar um ou mais desfechos, tais como contagem de abscessos e/ou nódulos, presença de nódulos inflamatórios, níveis de dor, qualidade de vida, segurança e custos. As bases de dados consultadas serão: *Medical Literature Analysis and Retrieval System Online* (MEDLINE, Interface OVID), *Excerpta Medica DataBASE* (EMBASE), Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS), *Cumulative Index to Nursing and Allied Health Literature* (CINAHL, interface EBSCO), *Psychological Abstracts* (PsycINFO, interface EBSCO), *Web of Science* (WoS) e *Source-Neutral Abstract and Citation Database* (Scopus). Os processos de triagem, seleção e extração serão conduzidos por pesquisadores independentes e previamente treinados. O risco de viés será avaliado por meio dos instrumentos *Risk of Bias 2.0* e *ROBINS-I*. Os resultados serão combinados em uma síntese qualitativa e quantitativa, com a realização de análises de especificidade e subgrupos.

Descritores: Hidradenite Supurativa; Dermatopatias; Adalimumab; Clindamicina; Rifampina; Falha de Tratamento.

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INTRODUCTION

Hidradenitis Suppurativa (HS), also known as inverse acne, is a chronic, inflammatory, recurrent skin disorder affecting the hair follicles of post-pubertal individuals. Its clinical presentation is typically painful due to the presence of inflammatory nodules, abscesses, fistulas, and comedones in various areas of the body, with a predilection for the axillary, genital, and mammary regions[1,2].

The diagnosis of HS is based on the identification of typical lesions, evaluation of affected regions, and monitoring for recurrence[2]. The primary diagnostic criterion is a history of painful, purulent lesions occurring at least twice in six months, and the secondary diagnostic criterion is a family history of the disease[3].

Given the characteristics of the disease, early initiation of HS treatment is associated with better outcomes. Therapeutic management of HS requires the combination of several multidisciplinary approaches capable of addressing inflammation control, pain, and comorbidities[4]. The Brazilian Consensus identifies topical, systemic, and biologic drug alternatives for the treatment of HS. Clindamycin used alone or in combination with antibiotics such as rifampicin, is the most common topical therapeutic option[5,6].

Hidradenitis suppurativa often presents in moderate to severe forms with resistance to topical or oral antibiotic therapies. Biologic therapies have therefore emerged as the treatment of choice for more resistant forms of the disease[4]. Among these, adalimumab stands out as a tumor necrosis factor-alpha antagonist indicated not only for the treatment of HS but also for other high prevalence diseases such as rheumatoid arthritis, psoriasis, and Crohn's disease[7].

Adalimumab is a recent therapeutic alternative for HS that has demonstrated satisfactory efficacy in treating the disease, particularly with the potential to reduce inflammatory nodules within 12 weeks and improve the quality of life in patients diagnosed with moderate to severe clinical presentations[8,9]. However, the information available on its effects varies widely in the literature in terms of study design, outcomes, and comparators.

Although there is a systematic review of randomized clinical trials testing the effects of adalimumab on HS[9], there is still no systematic evidence review that includes and compares the most common topical and biologic alternatives for HS treatment, covering both experimental and real-world approaches. Conducting a study with such characteristics will advance knowledge for therapeutic decision-making based on the synthesis of robust evidence encompassing the available alternatives for the treatment of HS.

With a focus on achieving the necessary reproducibility and internal validity for systematic reviews, a protocol was developed to define the objectives, methodological approaches, and analytic methods that will be used to conduct the study.

Based on the presented scenario and gaps, the systematic review described in this protocol aims to evaluate the efficacy, safety, pain, and quality of life associated with the use of adalimumab, clindamycin, and/or rifampicin for the treatment of HS.

METHOD

The study is based on the concept that a systematic review is an investigation that follows an explicit methodological process to answer clearly defined research questions. This is achieved by searching for, critically appraising, and analyzing the evidence available in the literature. The analytical perspective may be qualitative or quantitative; in the presence of comparable quantitative evidence, there is the potential to conduct meta-analyses to assess the weight and impact of the interventions studied[10,11].

The methodological process will follow the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions[10]. The systematic review will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). This protocol will be reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015[12]. This protocol has been prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO) under the registry code CRD42023426613.

Review question and outcomes

The PICO strategy was used to formulate the research question of this review, with the acronym considered in the following elements described in Figure 1.

PICO STRATEGY		TYPES OF STUDY TO BE ANALYZED
P (Population)	Adults diagnosed with hidradenitis suppurativa	
I (Intervention)	Use of adalimumab, clindamycin, and/or rifampicin	
C (Control)	No drug treatment or use of placebo; Drug treatment without adalimumab, clindamycin, or rifampicin; Clindamycin and/or rifampicin, compared to the use of adalimumab.	a) Prospective or retrospective cohort studies; b) Randomized clinical trial or randomized clinical trial of equivalence; c) Cost-effectiveness and cost-utility economic analyses.
O (Outcome)	Number of nodules, fistulas, and/or abscesses; Presence of nodules, fistulae, and/or abscesses; Pain; Quality of life; Safety; Cost of treatment.	

Figure 1 – Description of the PICO strategy used in the review. Fortaleza, CE, Brazil, 2023

Therefore, the research question for this review will be: "What are the effects of using adalimumab, clindamycin, and/or rifampicin in adults diagnosed with hidradenitis suppurativa compared with no treatment or use of standard treatment in terms of presence/number of nodules, fistulas, and/or abscesses, pain, quality of life, safety, and cost?"

Eligibility criteria, search strategies, and sources of information

The eligibility criteria follow the research question defined by the PICO strategy. Thus, the inclusion criteria are as follows: include adults diagnosed with hidradenitis suppurativa; be a prospective or retrospective cohort study, a randomized clinical trial, or a randomized clinical trial of equivalence; address the use of adalimumab, clindamycin, and/or rifampicin for the treatment of hidradenitis suppurativa; and evaluate the role of the listed drug treatments on one of the outcomes of interest in this study. An exclusion criterion is the inclusion of the pediatric population without the ability to separate their results from those presented for the adult population.

Search strategies will include database queries and manual searches. The following databases will be included: Medical Literature Analysis and Retrieval System Online (MEDLINE, OVID interface), *Excerpta Medica* Database (EMBASE), *Literatura Latino-Americana e do Caribe em Ciências da Saúde* (LILACS), Cumulative Index to Nursing and Allied Health Literature (CINAHL, EBSCO interface), Psychological Abstracts (PsycINFO, EBSCO interface), Web of Science Core Collections (WoS), and Source-Neutral Abstract and Citation Database (Scopus). Medical Subject Headings (MeSH) keywords will be used to establish search strategies in the databases. The following MeSH keywords will be used: "Hidradenitis Suppurativa", "Suppurative Hidradenitis", "Skin Diseases, Bacterial", "Skin Diseases", "Abscess", "Adalimumab", "Rifampin", "Clindamycin", "Patient Safety", "Treatment Outcome", "Evaluation of Efficacy-Efficacy of Interventions". The terms are adapted to the vocabulary of each database consulted. In addition, they will be combined using the Boolean operators "AND", "OR", and "NOT" to generate specific search strategies for each data source (Table 1). No language or language restriction is applied. The definition and refinement of the search strategies adopted were supported by a librarian with expertise in conducting systematic reviews.

A manual search will be conducted using two strategies: checking the reference lists of publications included in the final sample of the systematic review and accessing issues published in the last five years in peer-reviewed journals in the field of dermatology.

All searches will be conducted by one researcher who will record the date, time, and results of the searches.

Table 1 - Search strategies. Fortaleza, CE, Brazil, 2023

DATABASES	SEARCH STRATEGIES
MEDLINE, OVID Interface	"Hidradenitis Suppurativa" OR "Suppurative Hidradenitis" OR "Acne inversa" AND (Adalimumab OR "adalimumab effects") OR (rifampin OR rifampicin) OR clindamycin AND ("patient Safety" AND "Comparative Effectiveness Research" AND "Treatment Outcome" OR "Cost-Benefit Analysis" OR "Cost-Effectiveness Evaluation" OR "Evaluation of the Efficacy-Effectiveness of Interventions" OR Effectiveness OR Efficacy OR "Evaluation of Results of Therapeutic Interventions") AND abscess {Including Related Terms}
EMBASE	(('suppurative hidradenitis'/exp OR 'suppurative hidradenitis' OR 'suppurative hidradenitis':ti OR 'hidradenitis suppurativa severity score system'/de OR 'hidradenitis suppurativa clinical response'/de) AND 'adalimumab'/de AND 'rifampicin'/de AND 'clindamycin'/de AND 'skin abscess'/de AND 'patient safety'/de OR 'cost benefit analysis'/de OR 'quality of life'/de) AND ([adult]/lim OR [middle aged]/lim OR [young adult]/lim) AND 'article'/it AND ('adalimumab'/dd OR 'antibiotic agent'/dd OR 'clindamycin'/dd OR 'rifampicin'/dd) AND ('abscess'/dm OR 'adverse event'/dm OR 'allergic reaction'/dm OR 'anus fistula'/dm OR 'drug eruption'/dm OR 'fistula'/dm OR 'suppurative hidradenitis'/dm) AND ('clinical trial topic'/de OR 'cohort analysis'/de OR 'comparative effectiveness'/de OR 'controlled clinical trial'/de OR 'controlled clinical trial topic'/de OR 'controlled study'/de
LILACS	("hidradenitis suppurativa") AND (adalimumab) OR (rifampin) OR (rifampicin) OR (clindamycin) AND (fulltext:("1") AND db:("LILACS") AND mj:("Hidradenite Supurativa" OR "Glândulas Apócrinas" OR "Qualidade de Vida" OR "Axila" OR "Estudos Retrospectivos" OR "Pesquisa Participativa Baseada na Comunidade" OR "Doença Nodular Cutânea" OR "Antibacterianos") AND type_of_study:("prevalence_studies" OR "screening_studies" OR "risk_factors_studies" OR "diagnostic_studies" OR "evaluation_studies" OR "observational_studies" OR "clinical_trials" OR "etiology_ studies" OR "incidence_studies" OR "prognostic_studies" OR "systematic_reviews") AND limit:("humans" OR "adult") AND type:("article"))
CINAHL, interface EBSCO	TI "Hidradenitis Suppurativa" OR TI "Suppurative Hidradenitis" OR TX "Acne inversa" AND TX (Adalimumab OR "Adalimumab Effects") OR TX (Rifampin OR Rifampicin) OR TX Clindamycin AND TX ("Pacient Safety" AND "Comparative Effectiveness Research" AND "Treatment Outcome" OR "Cost-Benefit Analysis" OR "Cost-Effectiveness Evaluation" OR "Evaluation of the Efficacy-Effectiveness of Interventions" OR Effectiveness OR Efficacy OR "Evaluation of Results of Therapeutic Interventions") AND TX Abscess
PsycINFO, interface EBSCO	"Suppurative hidradenitis" OR Title: "hidradenitis suppurativa" OR Any Field: hidradenitis AND Any Field: "quality of life" AND Any Field: skin disease* AND Any Field: abscess AND Any Field: fistula AND Any Field: treatment outcome* AND Any Field: "patient safety" AND Any Field: Cost Benefit Analysis AND Any Field: Cost Efectiveness Analysis
Web of Science Core Collections	"Hidradenitis Suppurativa" (Keyword Plus ®) or "Suppurative Hidradenitis" (Keyword Plus ®) or "Acne inversa" (Keyword Plus ®) and Adalimumab (Tópico) or Rifampin (Tópico) or rifampicin (Tópico) and clindamicym (Tópico) and "Comparative Effectiveness" (Tópico) and "Cost-Benefit Analysis" (Tópico) and "Cost of Illness" (Tópico) and Artigo (Tipos de documento) and Artigo (Tipos de documento) and Dermatology or Nursing or Health Care Sciences Services or Economics (Categorias da Web of Science) and Dermatology or Nursing or Economics or Health Care Sciences Services or Health Policy Services (Categorias da Web of Science)
Scopus	(TITLE ("hidradenitis suppurativa") OR TITLE ("Suppurative Hidradenitis") OR TITLE-ABS-KEY ("Acne inversa") AND TITLE-ABS-KEY ("bacterial skin infection") OR TITLE-ABS-KEY ("skin disease") OR TITLE-ABS-KEY ("inflammatory skin conditions") OR TITLE-ABS-KEY ("skin inflammation") AND TITLE-ABS-KEY (adalimumab) OR TITLE-ABS-KEY (rifampin) OR TITLE-ABS-KEY (rifampicin) OR TITLE-ABS-KEY (clindamycin) AND TITLE-ABS-KEY (abscess) AND TITLE-ABS-KEY ("Treatment Outcome") OR TITLE-ABS-KEY (effectiveness) OR TITLE-ABS-KEY (efficacy)

Screening and selection of studies

The results of the searches in the listed databases are imported into the Zotero software, where duplicates are removed. The references are then imported into the Rayyan software for screening.

All references imported into the Rayyan software will be evaluated by two independent researchers. They will be trained and assessed in pilot tests with the goal of achieving at least 75% agreement in their decisions regarding the inclusion of potentially relevant studies. Two pairs of reviewers will participate in the screening and selection process, with each pair responsible for evaluating the same references in the screening and selection phases.

After reaching this threshold of agreement between the reviewers, the titles and abstracts of the non-duplicated references are read. At this stage, the references are checked to ensure that they meet all the inclusion criteria established for this study. Discrepancies will be resolved by a third researcher who will be the coordinator of this systematic review. The decision-making process will consider the appropriateness of the reference to the eligibility criteria established in this protocol. References considered potentially eligible will be thoroughly analyzed by two independent researchers to i) confirm compliance with the inclusion criteria and ii) assess the exclusion criteria. Again, discrepancies will be decided with the involvement of the same third reviewer, using the same pre-established criteria as in the previous stage. Reasons for not including references are recorded and compiled.

The results of the search, screening, and study selection processes are compiled and presented in the PRISMA flowchart[12].

Data extraction

The data extraction instrument for articles included in the final study sample will include the following elements: bibliometric characteristics; sociodemographic and clinical profile of participants; methodological design; systems used for randomization, if relevant; therapies used, including dosage; quantitative and qualitative data on outcomes; and other relevant information. The investigators responsible for data extraction will be those who achieve at least 75% concordance in pilot testing. The data extraction process will be conducted by two independently trained researchers, and the extraction spreadsheets will be reviewed and compared by the review supervisor.

Risk of bias assessment

Non-randomized intervention studies will be assessed using the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool, which includes the following domains: confounding, selection of participants, classification of non-randomized interventions, departures from intended interventions, missing data, outcome measurement, and selective reporting. Bias in randomized intervention trials will be assessed using the Risk of Bias 2.0 (RoB 2.0) tool, which includes five domains: randomization process, departures from intended interventions, missing outcome data, outcome measurement, and selective reporting.

The instruments will be applied by two independent researchers to the studies included in the final sample. Disagreements will be resolved in consultation with a third reviewer.

Data organization and analysis

The data extracted from the studies included in the final sample will be transformed into information and combined in a narrative synthesis to summarize the characteristics of the studies, the therapeutic alternatives used to treat adult hidradenitis suppurativa, dosages, sociodemographic characteristics of participants, clinical conditions before and after treatment, pain assessment, quality of life, costs, and expenses associated with the treatments. This synthesis will provide a comprehensive overview of the efficacy of adalimumab, clindamycin, and rifampicin in the treatment of adult hidradenitis suppurativa. It is planned to integrate this information into subgroups based on experimental and real-world designs, use of similar interventions, treatment duration, and outcomes. Results will be presented in tables.

Based on a previously conducted non-systematic search to assess the feasibility of this review, it is estimated that it will be relevant to also perform a quantitative synthesis of the findings. This analytical approach will be crucial to measure the magnitude and direction of the effects of therapeutic alternatives in the treatment of adult hidradenitis suppurativa, addressing significant gaps in the literature, clinical practice, and public health policy decision-making.

The quantitative synthesis will be preceded by an analysis of the clinical and methodological heterogeneity of the studies included in the review. The similarity between studies will be assessed by the following elements: sociodemographic and clinical characteristics of the population, clinical

condition/disease stage, dosage used, methodological design, follow-up period, sample size, losses to follow-up, and effect measures used. After appropriate methodological and clinical homogeneity has been established, a meta-analysis is performed to determine the size and direction of the effect of the therapeutic alternatives studied. For qualitative outcomes, relative risk and hazard ratio with 95% confidence intervals will be considered as effect measures. For quantitative outcomes, the weighted mean or mean difference will be used. Heterogeneity is assessed using the I^2 statistic. Review Manager software version 5.4.1 will be used for this analysis.

Because of the potential variability in treatments, dosages, designs, and outcomes, subgroup analyses will be performed. A priority for this analysis is the comparison of observational studies, which are considered real-world because of their potential contribution to public policy planning. In addition, a sensitivity analysis is planned considering the methodological quality of the studies and the weight of the studies for effect estimation.

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