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Efficacy and safety of Hyperthermia for Cutaneous warts: Systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023110082

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 November 2023 and was last updated on 20 November 2023.

INTRODUCTION

Review question / Objective Warts, caused by the human papillomavirus, can regress spontaneously or exhibit a persistent clinical course. We divide them into planter warts, common warts, cutaneous warts etc. There are many different options to treat warts currently, including surgical excision, cryotherapy, chemical ablation and hyperthermia. Hyperthermia is an effective, safe method for the treatment of warts compared to traditional treatments. Thermotherapy at low and moderate temperatures can stimulate a local immune response, therefore it can reduce the recurrence rate of warts. However, at present, no meta-analysis has examined hyperthermia for warts caused by HPV infection. We analysed existing studies, compared the efficacy of hyperthermia , recorded recurrence rates and adverse events to fill this gap.

Condition being studied Viral warts can occur at any age, but are rare in infants and young children. It is estimated that the overall prevalence of viral warts in the population is 7% to 12%, while 50% to 80% of sexually active individuals can carry HPV. Some warts are prone to recurrence, and the particularly growth sites are easily to pain, which can cause difficulties in patients' daily lives and psychology., Different treatments may have distinct outcomes. We need to conduct an meta-analysis from the following aspectes, such as warts' clearance, recuurence, patient satisfaction, pain degree, adverse events, quality of life during treatment, and the cost-effectiveness ratioadverse events.

METHODS

Participant or population RCT trial comparing hyperthermia with other treatments in subjects with skin warts and warts were diagnosed by clinical or pathological. Previous treatment was allowed.

Intervention Hyperthermia has various controllable energy sources, including radiofrequency,

microwave and laser. Mild hyperthermia can stimulate a local immune response, higher hyperthermia can directly kill HPV virus.

Comparator Comparator includes cryotherapy, placebo, chemical destructive treatments.

Study designs to be included Study inclusion selection criteria were (1) only studies designed as RCT; (2) having original data providing risk ratio (RR) estimates with confidence intervals (CIs) or enough data to calculate them; (3) For subjects: warts were diagnosed by clinical or pathological. Previous treatment was allowed; (4) Hyperthermia reported in at least 1 comparison treatment group; and 5) versus a placebo, cryotherapy or chemical ablation.

Eligibility criteria Study inclusion selection criteria were (1) only studies designed as RCT; (2) having original data providing risk ratio (RR) estimates with confidence intervals (CIs) or enough data to calculate them; (3) For subjects: warts were diagnosed by clinical or pathological. Previous treatment was allowed; (4) Hyperthermia reported in at least 1 comparison treatment group; and 5) versus a placebo, cryotherapy or chemical ablation. The exclusion criteria of this study were as follows: (1) reviews, comments, case reports, letters or conference abstracts; (2) duplicate studies; (3) articles without useable data; (4) articles not involving human studies.

Information sources We searched four dabetes included of Pubmed, Embase, Web of Science, the Cochrane Library.

Main outcome(s) Main outcomes include overall clearance of people, clearance rates of the target lesions, pain degree, adverse events and recurrence rate.

Quality assessment / Risk of bias analysis Two reviewers will independently assesses 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 5.3Use risk assessment tools- Review manager 5.4 to evaluate from six aspects, including stochastic method; assignment hidden, blinding method, data integrity, selective reporting, "+" means low risks, "-" means high risks, "?" means unclear risks.

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 STATA software for Mac v15.0 (Stata Corp., College Station, Texas) [module "meta"] and R studio v1.0.136 (The R Foundation for Statistical Computing) [package "meta v4.2"].

Subgroup analysis We will consider subgroups, such as different types of control groups, warts types.

Sensitivity analysis An influence analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies. Statistical analysis will be conducted using STATA software for Mac v15.0 (Stata Corp., College Station, Texas) [module "meta"].

Country(ies) involved China.

Keywords cutaneous warts; hyperthermia; thermotherapy; laser; cryotherapy; HPV; virus infection; meta-analysis; systematic review.

Contributions of each author

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