INPLASY PROTOCOL

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Review Stage at time of this submission: The review has not yet started.

Conflicts of interest:
None.

A comparison of efficacy/adverse effects of laser versus topical timolol for infantile hemangioma

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Review question / Objective: RCT literature reporting efficacy or adverse effects of laser or topical timolol interventions in infants who are diagnosed with hemangioma.

Condition being studied: To study the efficacy of laser and topical timolol in the treatment of infantile hemangioma and the incidence of adverse reactions, and play a guiding role in clinical medication.

Information sources: PubMed, Embase, Cochrane, wiley online library, Elsevier, Web of Science, WanFang Data, CNKI. Aug, 15th, 2020.

INTRODUCTION

Review question / Objective: RCT literature reporting efficacy or adverse effects of laser or topical timolol interventions in infants who are diagnosed with hemangioma.

Rationale: For bivariate variables, odds ratios under 95% confidence intervals were calculated, with significant statistical significance for P <0.05, relative risk ratios under 95% confidence intervals were calculated for the monotherapy group and the blank control group, and p<0.05 was statistically significant if the 95% confidence intervals were not coincident.

Condition being studied: To study the efficacy of laser and topical timolol in the treatment of infantile hemangioma and the incidence of adverse reactions, and play a guiding role in clinical medication.

METHODS

Search strategy: (hemangioma OR hemangiomas) AND (infant OR infants OR infantile) AND (laser OR timolol).

Participant or population: Infants who are diagnosed with hemangioma.

Intervention: Laser/Topical timolol.

Comparator: Laser/Topical timolol/Observation.

Study designs to be included: RCT or Retrospective study (If insufficient, case reports and case analysis will be included).

Eligibility criteria: RCT literature reporting efficacy or adverse effects of laser or topical timolol interventions in infants with confirmed hemangioma.

Information sources: PubMed, Embase, Cochrane, wiley online library, Elsevier, Web of Science, WanFang Data, CNKI. Aug, 15th, 2020.

Main outcome(s): Efficacy of regression of hemangioma/adverse effect(without edema and other temporary adverse effect).

Data management: After screening the eligible articles, Cochrane bias risk assessment was conducted for the RCT articles and NOS literature quality assessment was conducted for the retrospective study. Two independent researcher will extract the literature data (the first author's surname, year of publication, study population(nationality), protocol and dose, sample size, course of treatment, age(mean/range), sex ratio, duration of follow-up, disease area, tumor type, outcome indicators, outcomes, and adverse events) by using tables. In case of disagreement, a third researcher will intervene.

Quality assessment / Risk of bias analysis: Cochrane bias risk assessment was conducted for the RCT articles and NOS literature quality assessment was conducted for the retrospective study, a quality score of NOS ranged from 0 to 9 stars as obtained by summing the standards, and the high-quality CS was defined as a CS with a minimum of 7 stars. The above assessment will be carried out by two independent researchers, and a third one will intervene in case of disagreement.

Strategy of data synthesis: We used the software package Review Manager 5.3.5 for analysis. For dichotomous variables, OR under 95%CI and RR under 95%CI were calculated for monotherapy versus blank control. Heterogeneity was assessed by inconsistent I^2 measurements. Heterogeneity was statistically significant if I^2 was >50%. When I^2 50%, the results of the random effects model are more desirable.

Subgroup analysis: Hemangiomas are especially prone to occur in premature infants, low birth weight infants, Caucasians and females, and are closely related to heredity. Moreover, the effect of external medication is correlated with treatment duration, site of tumor, follow-up time and tumor type, all of which are considered as the basis for subgroup analysis.

Sensibility analysis: For statistically significant heterogeneity, subgroup analysis and sensitivity analysis are used.

Language: English/Chinese.

Country(ies) involved: China.

Keywords: hemangioma; timolol; laser; Meta-analysis.

Contributions of each author:
Author 1 - Huaxu Huang - Data summary, data graph processing, article writing, post-modification, data reviewer 1.
Author 2 - Xuanfeng Chen - Subject ideas provided, data collection, data reviewer 2.
Author 3 - Beichen Cai - Literature screening.
Author 4 - Jiaqi Yu - Literature screening.
Author 5 - Biao Wang - Post-modification, data reviewer 3 (when disagreements arise).