INPLASY PROTOCOL

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Conflicts of interest:
None.

Impact of ultrasound in diagnosis of hydatidiform mole in early pregnancy: a protocol of systematic review

Li, L[1]; An, CY[2].

Review question / Objective: **Does ultrasound accurately diagnose hydatidiform mole (HM) in early pregnancy (EP)?**
Condition being studied: **Ultrasound; hydatidiform mole; early pregnancy.**
Information sources: **This study will perform search strategy from literature sources and it will consist of two steps. First, a comprehensive search of potential studies will be carried out in Cochrane Library, MEDLINE/PUBMED, EMBASE, PsycINFO, WANGFANG, and CNKI from inception to the present. A sample of search strategy for Cochrane Library is presented. We will modify similar search strategy for other electronic databases. Second, conference abstract, ongoing studies in clinical trial registry and reference lists of essential studies will be identified for additional studies. No language and publication status limitations will be occupied in this study.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 August 2020 and was last updated on 18 August 2020 (registration number INPLASY202080080).

INTRODUCTION

Review question / Objective: **Does ultrasound accurately diagnose hydatidiform mole (HM) in early pregnancy (EP)?**

Condition being studied: **Ultrasound; hydatidiform mole; early pregnancy.**

METHODS

Participant or population: **We will consider female participants (more than 18 years old) with HM in EP in this study. No limitations were applied to race, country, and educational background.**

Intervention: Index test: ultrasound was applied in diagnosis of HM in EP.

Comparator: Reference test: patients were diagnosed by histological-proven HM in EP.

Study designs to be included: We will consider case-controlled studies (CCSs) for inclusion that reported the impact of ultrasound in diagnosis of HM in EP.

Eligibility criteria: We will consider CCSs for inclusion that reported the impact of ultrasound in diagnosis of HM in EP.

Information sources: This study will perform search strategy from literature sources and it will consist of two steps. First, a comprehensive search of potential studies will be carried out in Cochrane Library, MEDLINE/PUBMED, EMBASE, PsycINFO, WANGFANG, and CNKI from inception to the present. A sample of search strategy for Cochrane Library is presented. We will modify similar search strategy for other electronic databases. Second, conference abstract, ongoing studies in clinical trial registry and reference lists of essential studies will be identified for additional studies. No language and publication status limitations will be occupied in this study.

Main outcome(s): Outcomes are sensitivity, specificity, mistake diagnostic rate, and omission diagnostic rate.

Data management: All essential data will be collected independently by two researchers using a developed and standardized sheet to document study information (e.g. title, first author, year, study design, sample size, et al), patient characteristics (e.g. age, gender, stage of tumors, et al), outcome measurements, index and reference tests, main findings, and other important information. If there are conflicts between two researchers, a third researcher will be invite to solve them, and a final decision will be reached. In addition, any lacking or missing information will be requested by obtaining original study authors via email or fax.

Quality assessment / Risk of bias analysis: Two researchers will independently appraise study quality of CCSs using Quality Assessment of Diagnostic Accuracy Studies tool-2. Any divergence will be resolved with the help of a third researcher through discussion or consultation.

Strategy of data synthesis: Stata 12.0 software will be applied to conduct the statistical analysis. We will estimate effect size as descriptive statistics and 95% confidence intervals. Levels of heterogeneity will be identified using I2 statistic. I2 ≤ 50% means acceptable heterogeneity, and a fixed-effects model will be employed for data pooling; while I2 >50% indicates obvious heterogeneity, and a bivariate random-effects model will be placed for data synthesis. If considerable heterogeneity is detected, we will conduct a subgroup analysis to find out its sources. We will carry out the pooled sensitivity, specificity, mistake diagnostic rate, omission diagnostic rate, and draw the hierarchical summary receiver operating characteristic curve to appraise diagnostic accuracy of ultrasound for HM in EP. If permits, we will pool the data and perform meta-analysis. If statistical synthesis is not possible, we will report its findings in forest plot and narrative description.

Subgroup analysis: We will conduct subgroup analysis in accordance with different study information, study characteristics, and index and reference tests.

Sensibility analysis: We will perform sensitivity analysis to check stability of merged outcome results by removing low quality studies, or insufficient sample size.

Country(ies) involved: China.

Keywords: Hydatidiform mole; pregnancy; ultrasound; impact.

Contributions of each author:
Author 1 - Li Li.
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