INPLASY PROTOCOL

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

Conflicts of interest:
None.

Low-dose CT combined mammography in diagnosis of overflow breast disease: A protocol of systematic review

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Review question / Objective: **Is low-dose CT combined mammography (LDCTMG) accurate in diagnosis of overflow breast disease (OBD)?**
Condition being studied: **Low-dose CT; mammography; overflow breast disease.**
Information sources: **Electronic databases. We will perform primary literature search from inception to the present in The Cochrane Library, the Cochrane Register of Diagnostic Test Accuracy Studies, PUBMED, EMBASE, Web of Science, CINAHL, CNKI, and WANGFANG. We will not place restrictions to the language and publication status. We will build detailed search strategy of PUBMED. We will adapt similar search strategies for other electronic databases. Other resources. We will carry out secondary literature search from other sources, such as conference proceedings, ongoing studies from clinical study registry, and reference lists of included study.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 May 2020 and was last updated on 31 May 2020 (registration number INPLASY202050116).

INTRODUCTION

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METHODS

Participant or population: **All female adult participants who were diagnosed as OBD will be included in this study, in spite of country, race, and different characteristics of OBD.**

Intervention: Index test: All participants received any forms of LDCTMG in diagnosis of OBD.

Comparator: Reference test: All subjects received approved histopathological test in diagnosis of OBD as a comparator.

Study designs to be included: We will include case-controlled studies (CCSs) on evaluating the accuracy of LDCTMG is accurate in diagnosis of OBD.

Eligibility criteria: We will include case-controlled studies (CCSs) on evaluating the accuracy of LDCTMG is accurate in diagnosis of OBD. However, other studies will be excluded, such as review, comments, case studies, non-clinical study, and uncontrolled study.

Information sources: Electronic databases. We will perform primary literature search from inception to the present in The Cochrane Library, the Cochrane Register of Diagnostic Test Accuracy Studies, PUBMED, EMBASE, Web of Science, CINAHL, CNKI, and WANGFANG. We will not place restrictions to the language and publication status. We will build detailed search strategy of PUBMED. We will adapt similar search strategies for other electronic databases. Other resources. We will carry out secondary literature search from other sources, such as conference proceedings, ongoing studies from clinical study registry, and reference lists of included study.

Main outcome(s): Outcome measurements comprise of sensitivity, specificity, precision, accuracy, false positive rate, true positive rate, false negative rate, true negative rate, and diagnostic odds ratio.

Quality assessment / Risk of bias analysis: Two researchers will independently assess risk of bias for included study by a Revised Tool for the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2). Any doubt between two researchers will be cleared up by a third researcher through consultation.

Strategy of data synthesis: We will perform data analysis using RevMan V.5.3 software and Stata V.12.0 software. For each eligible study, we will present outcome indicators as separate binary classifiers and record specifics for dichotomization. To visualize outcome results, we will present them as descriptive statistics and 95% confidence intervals. We will carry out I2 test to check heterogeneity across studies. I2 ≤ 50% means minor heterogeneity, and Mantel-Haenszel fixed-effects model will be used. On the other hand, I2 >50% indicates substantial heterogeneity, and Mantel-Haenszel random-effects model will be placed. We will construct 2 x 2 tables to estimate reference standard and test outcome, and will estimate and conduct a descriptive forest plot and a summary receiver operating characteristic plot. If necessary, we will conduct meta-analysis based on the sufficient similarity in characteristics of study and patient, index and reference tests, and outcome indicators. If meta-analysis is deemed not to be conducted, we will report study results by a narrative description.

Subgroup analysis: This study will carry out a subgroup analysis based on the different patient characteristics, index and reference tests, and outcome indicators.

Sensibility analysis: This study will perform a sensitivity analysis to examine the stability of study findings by excluding low quality study.

Country(ies) involved: China.

Keywords: Overflow breast disease; mammography; CT; diagnosis.

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