INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Meta-analysis of Kangai injection combined with radiotherapy and chemotherapy in the treatment of gynecological malignant tumors

Guo, J[1]; Chen, YH[2]; Li, CX[3]; Ling, X[4]; Wang, PP[5]; Yang, YQ[6]; Zhang, YY[7].

Review question / Objective: **This study systematically evaluated the clinical efficacy and safety of Kangai injection combined with radiotherapy and chemotherapy in the treatment of gynecological malignant tumors. The subjects of the study were patients with clinical diagnosis of ovarian cancer, cervical cancer, and endometrial cancer. The experimental group was given Kang'ai injection combined with radiotherapy and chemotherapy, while the control group was given conventional chemotherapy. The primary outcome was the overall clinical response rate. Secondary outcomes included quality of life, body mass, indicators of immune function, and adverse events.**
Information sources: **Eight databases including CNKI, Wan fang Database, VIP Chinese Database, China Biomedical Literature Service System, EI, Springer, PubMed, The Cochrane Library were searched before May 2022.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 June 2022 and was last updated on 15 June 2022 (registration number INPLASY202260063).

INTRODUCTION

Review question / Objective: **This study systematically evaluated the clinical efficacy and safety of Kangai injection combined with radiotherapy and chemotherapy in the treatment of gynecological malignant tumors. The subjects of the study were patients with clinical diagnosis of ovarian cancer, cervical cancer, and endometrial cancer. The experimental group was given Kang'ai**

injection combined with radiotherapy and chemotherapy, while the control group was given conventional chemotherapy. The primary outcome was the overall clinical response rate. Secondary outcomes included quality of life, body mass, indicators of immune function, and adverse events.

Condition being studied: The three most common gynecological malignancies are "Cervical cancer, Ovarian cancer and Endometrial Carcinoma ", which have caused great damage to the physical and mental health of women. large and irreversible damage.this paper comprehensively searches the clinical trials of KAI combined with chemoradiotherapy in the treatment of cervical cancer, ovarian cancer and endometrial cancer and conducts Meta-analysis to objectively evaluate the clinical efficacy and safety of KAI combined with radiotherapy and chemotherapy in the treatment of gynecological malignant tumors, to provide a reference for the clinical decision-making and rational drug use of KAI in the treatment of gynecological malignant tumors.

METHODS

Search strategy: Eight databases including CNKI, Wan fang Database, VIP Chinese Database, China Biomedical Literature Service System, EI, Springer, PubMed, The Cochrane Library were searched before May 2022; The retrieval strategy is "subject heading+ free word", Chinese search terms are "Kangai injection ", "cervical cancer", "ovarian cancer" and "endometrial cancer", English search terms Pub med, Cochrane Library, Springer, EI databases were searched for "Kang ai injection" "Ovarian cancer" "Cervical cancer" "Endometrial carcinoma".

Participant or population: Inclusion criteria: Randomized controlled trials (RCTs) of KAI adjuvant treatment of cervical cancer, ovarian cancer, and endometrial cancer are limited to Chinese and English literature

Intervention: The observation group was given Kang ai injection on the basis of the control group.

Comparator: The control group was treated with conventional radiotherapy and chemotherapy, including 8 methods (NO1-NO8): NO1.Radiotherapy alone; NO2.DC(Docetaxel + carboplatin); NO3.Docetaxel + cisplatin; NO4. Docetaxel + Lo platin; NO5.TP(Paclitaxel + cisplatin); NO6. Paclitaxel + carboplatin; NO7.Cisplatin + 5-fluorouracil; NO8.Three-dimensional conformal radiotherapy + simultaneous cisplatin single-agent chemotherapy.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: None.

Information sources: Eight databases including CNKI, Wan fang Database, VIP Chinese Database, China Biomedical Literature Service System, EI, Springer, PubMed, The Cochrane Library were searched before May 2022

Main outcome(s): The primary outcomes was Clinical Total effective rate;Secondary Outcomes were Life quality improvement rate;Body weight improvement;Adverse reactions (gastrointestinal reactions, leukopenia), abdominal pain, diarrhea, thrombocytopenia, liver and kidney function damage);Immune function indicators (CD3+, CD4+, CD8+, CD4+/CD8+).

Additional outcome(s): Life quality improvement rate;Body weight improvement;Adverse reactions (gastrointestinal reactions, leukopenia), abdominal pain, diarrhea, thrombocytopenia, liver and kidney function damage);Immune function indicators (CD3+, CD4+, CD8+, CD4+/CD8+).

Data management: Two authors will independently extract data.Any disagreement will be resolved by discussion until consensus is reached or by

consuting a third author The folowina data will be extracted: author vear of publication country where the study was conducted study period original inclusion criteria total number of people included in the study, and so on.

Quality assessment / Risk of bias analysis: The Cochrane Risk of Bias Assessment Tool.

Strategy of data synthesis: R language was used for estimating risks of bias of included studies, data analysis, and plotting.

Subgroup analysis: Subgroup analyses are planned for indicators of immune function.

Sensitivity analysis: Sensitivity analysis for decreased white blood cells.

Country(ies) involved: China, The First Affiliated Hospital of Henan University of Traditional Chinese Medicine, Zhengzhou, 450046, China;Henan University of Traditional Chinese Medicine;The First Affiliated Hospital of Henan University of Traditional Chinese Medicine.

Keywords: Traditional Chinese Medicine Injection, Cervical Cancer, Ovarian Cancer, Endometrial Cancer, Systematic Review, Kangai Injection.

Contributions of each author:

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