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Investigating the effectiveness of esketamine in reducing depression for breast cancer patients after surgery

Submission date
20/08/2024

Recruitment status
No longer recruiting

Registration date
25/08/2024

Overall study status
Completed

Last Edited
22/08/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is one of the most common cancers among women worldwide, and while treatments can be effective, they often come with significant side effects. One of the most challenging side effects is depression, which can greatly affect patients' quality of life. Traditional antidepressants, though helpful, often take a long time to work and may cause unwanted side effects. To address this, researchers are exploring new treatment options. Esketamine, a medication that has recently shown promise, can improve mood quickly, making it a potentially valuable option for treating depression after breast cancer surgery. This study aims to investigate how effective Esketamine is in treating depression in breast cancer patients after surgery.

Who can participate?
Women who have undergone breast cancer surgery (specifically, a modified radical mastectomy) at the Cancer Hospital, Chinese Academy of Medical Sciences. The participants must have been treated at this hospital between July 2020 and March 2023.

What does the study involve?
Participants in the study will first have their depression levels assessed using a standard scale (Hamilton Depression Scale, HAMD-17) before their surgery. They will then be randomly assigned to one of two groups: one group will receive an injection of Esketamine, and the other group will receive a placebo (a substance with no active medication). Six months after surgery, the participants' depression levels will be reassessed through follow-ups conducted via the WeChat app.

What are the possible benefits and risks of participating?
The potential benefit for participants is the possibility of experiencing faster relief from depression if they receive Esketamine. However, as with any medication, there are risks of side effects, and the effectiveness of Esketamine specifically for this purpose is still being studied. Participants in the placebo group may not experience the same benefits, but their involvement is crucial to understanding whether Esketamine is genuinely effective.

Where is the study run from?
The study is being conducted at the First Affiliated Hospital of the University of South China, with follow-ups performed remotely using WeChat.

When is the study starting and how long is it expected to run for?
March 2020 to October 2023.

Who is funding the study?
The study is funded by several organizations, including the Natural Science Foundation of Hunan Province, the Wu Jieping Medical Foundation Clinical Research Special Fund, the NewRay Oncology Supportive Care Research Project, and the China Postdoctoral Science Foundation (China)

Who is the main contact?
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Study information

Scientific Title
A randomized, double-blind, controlled trial to evaluate the effect of esketamine on postoperative depressive symptoms in breast cancer patients undergoing modified radical mastectomy (Esketamine in Breast Cancer-Depression Randomized Trial)

Acronym
EBC-DRT

Study objectives
Esketamine can effectively reduce postoperative depressive symptoms in breast cancer patients undergoing modified radical mastectomy, with significant differences compared to the placebo group.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/12/2019, Ethics Committee of The First Affiliated Hospital of University of South China (69 Chuanshan Road, Shigu District, Hengyang, 421001, China; +44 734-8279018; nhfyllwyh@163.com), ref: No. 2020LL0304001

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Breast cancer with postoperative depressive symptoms

Interventions
This randomized, double-blind, controlled trial enrolled 108 breast cancer patients who underwent modified radical mastectomy between July 2020 and March 2023. All patients were assessed with the Hamilton Depression Scale (HAMD-17) prior to surgery. The trial collected patient demographics, including age, weight, height, and pathology type. The pathology type of all patients was confirmed by the hospital's pathology department to ensure data accuracy. A detailed treatment history of each patient, including type of surgery, chemotherapy, and radiotherapy, was meticulously recorded to ensure data completeness. The treatment history of all patients was provided by the treating physicians and subsequently cross-checked by study team members. Patients were consecutively recruited during the study period and randomly assigned to groups based on whether they received esketamine treatment. Esketamine injection (purchased from Jiangsu Hengrui Pharmaceutical Co., Ltd, Product No. KH080601) was administered to the experimental group (Group E), while the control group (Group C) received a

placebo . Additionally, patients were diagnosed using imaging and histological methods. The HAMD-17 scores for all patients were reassessed at 6 months postoperatively through WeChat-based follow-up.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Esketamine

Primary outcome(s)
Hamilton Depression Scale (HAMD-17) scores at baseline and 6 months postoperatively

Key secondary outcome(s)
1. HAMD-17 score changes at baseline (pre-surgery) and 6 months post-surgery
2. Patient demographic data (age, weight, height, pathology type)measured by review of patient medical records at the time of enrollment

Completion date
01/10/2023

Eligibility

Key inclusion criteria
1. HAMD-17 score between 8 and 24 (mild to severe depressive symptoms)
2. Age range between 18 and 65 years
3. American Society of Anesthesiologists (ASA) physical status classification of I-II
4. Confirmed diagnosis of breast cancer and planned unilateral radical mastectomy for breast cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
108

Key exclusion criteria
1. HAMD-17 score of greater than 24 or less than 7
2. Other psychiatric disorders (e.g., schizophrenia and bipolar disorder)
3. History of psychiatric disorders prior to the study
4. Patients who have used psychotropic medications or have other serious systemic illnesses (including serious heart, kidney, or liver disease)
5. Contraindication or allergy to the use of esketamine
6. Planned surgery other than radical mastectomy alone (e.g., reconstruction)

Date of first enrolment
01/07/2020

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of University of South China
69 Chuanshan Road, Shigu District
Hengyang
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Sponsor information

Organisation
The First Affiliated Hospital of University of South China

Funder(s)

Funder type
Government

Funder Name

Natural Science Foundation of the Hunan Province of China (Grant No. 2022JJ70143, 2022JJ70122)

Funder Name
Wu Jieping Medical Foundation Clinical Research Special Grant Fund (Grant No. 320.6750.2023-18-17)

Funder Name
Xinrui Tumor Support Therapy Research Project(Grant No. cphcf-2023-022)

Funder Name
The China Postdoctoral Science Foundation (Grant No. 2023M733955)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysedduring the current study will be available uponrequest from (Haifan Xu;3287917718@qq.com)

IPD sharing plan summary
Available on request