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Recruiting 

Prevention of Breakthrough CINV in Patients Receiving Moderately or Highly Emetogenic Chemotherapy

ClinicalTrials.gov ID  NCT06065722

Sponsor  Simon Williamson Clinic

Information provided by  Simon Williamson Clinic (Responsible Party)

Last Update Posted  2023-10-10

Study Details Tab

Study Overview

Brief Summary

The purpose of the proposed study is to provide a clinical approach to chemotherapy induced nausea and vomiting (CINV) prophylaxis in cycle 2 of moderately emetogenic chemotherapy or highly emetogenic chemotherapy for patients who developed breakthrough CINV after cycle 1 based on the available data in the literature as well as the recommendations provided by established guidelines

Detailed Description

Chemotherapy-induced nausea and vomiting (CINV) adversely affects patients' quality of life and may affect patients' treatment decisions. The emetogenicity of the chemotherapy administered and specific patient characteristics such as female gender, age, and history of low alcohol intake can increase a patients' risk for CINV.



Table 1. Patient-Related Risk Factors for Emesis Following Chemotherapy Major Factors Minor Factors
Female History of Motion Sickness Age < 50 years Emesis during past pregnancy History of prior low
chronic alcohol intake (<1 ounce of alcohol/day) Anxiety History of previous chemotherapy-induced
emesis

Significant and uncontrolled CINV may result in patients returning to the chemotherapy treatment facility one to three days post-chemotherapy for rehydration, or emesis or nausea control. If CINV cannot be controlled in an outpatient facility, patients may subsequently be treated in an emergency department or require hospitalization. Patients who have an electrolyte imbalance or those who have recently undergone surgery or radiation therapy, are at greater risk of experiencing serious complications from CINV.

The use of 5-hydroxytryptamine-3 (5-HT₃) receptor antagonists has improved the control of CINV. Additional improvement in the control of CINV has occurred with the use of neurokinin-1 (NK-1) receptor antagonists, and olanzapine, an antipsychotic which blocks multiple neurotransmitters in the central nervous system.

The primary endpoint used for studies evaluating various agents for the control of CINV has been complete response (CR) (no emesis, no use of rescue medication) over the acute (24 hours post-chemotherapy), delayed (24-120 hours), and overall (0-120 hours) periods. The combination of a 5-HT₃ receptor antagonist, dexamethasone, and a NK-1 receptor antagonist have improved the control of emesis in patients receiving either highly emetogenic chemotherapy (HEC) or moderately emetogenic chemotherapy (MEC) over a 120-hour period following chemotherapy administration.

The use of effective antiemetic agents in various clinical settings has been described in established guidelines from the Multinational Association of Supportive Care in Cancer (MASCC) and the European Society of Medical Oncology (ESMO), the American Society of Clinical Oncology (ASCO), and the National Comprehensive Cancer Network (NCCN).

The purpose of the proposed is to provide a clinical approach to CINV prophylaxis in cycle 2 of MEC or HEC for patients who developed breakthrough CINV after cycle 1 based on the available data in the literature as well as the recommendations provided by established guidelines.

Official Title

Akynzeo or Olanzapine for Patients Who Experience Breakthrough CINV in Patient Receiving Moderately or Highly Emetogenic Chemotherapy After First Cycle of Chemotherapy

Conditions

Chemotherapy Induced Nausea and Vomiting

Intervention / Treatment

- Drug: Akynzeo

Other Study ID Numbers

Study Start (Actual) ⓘ

2023-09-09

Primary Completion (Estimated) ⓘ

2023-12-31

Study Completion (Estimated) ⓘ

2023-12-31

Enrollment (Estimated) ⓘ

100

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Resource links provided by the National Library of Medicine

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>) related topics: [Nausea and Vomiting](https://medlineplus.gov/nauseaandvomiting.html) (<https://medlineplus.gov/nauseaandvomiting.html>)

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>) available for:
[Olanzapine](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Olanzapine) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Olanzapine>) [Olanzapine pamoate](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Olanzapine+pamoate) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Olanzapine+pamoate>)

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](#) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

Study Contact

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This study has 1 location

United States

Alabama Locations

 **Mount Olive, Alabama, United States, 35117**

Recruiting

Rudolph M Navari

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Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- CHEMOTHERAPY NAIIVE
- patient receiving moderately or highly emetogenic chemotherapy
- lung cancer
- breast cancer

Exclusion Criteria:

- PRIOR CHEMOTHERAPY for any cancer
- nausea or vomiting 24 hours prior to study entry

Ages Eligible for Study ?

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study ?

All

Accepts Healthy Volunteers ?

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ? : Supportive Care

Allocation ? : Randomized

Interventional Model ? : Parallel Assignment

Masking ? : Double (Participant, Investigator)

Masking Description: Double Blind

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Active Comparator: AKYNZEO for patient receiving MEC Add Akynzeo to 5HT3 And dexamethasone	Drug: Akynzeo <ul style="list-style-type: none"> • OLANZAPINE • Other Names: <ul style="list-style-type: none"> ◦ Olanzapine
Active Comparator: oLANZAPINE and Akynzeo to patients receiving highly emetogenic oLANZAPINE plus Akynzeo	Drug: Akynzeo <ul style="list-style-type: none"> • OLANZAPINE • Other Names: <ul style="list-style-type: none"> ◦ Olanzapine

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
COMPELETE RESPONSE, no vomiting or use of rescue medications	No vomiting or use of rescue medications for 5 days post chemotherapy	5 DAYS post chemot herapy

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Simon Williamson Clinic

Collaborators ⓘ

- Helsinn Healthcare SA

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2023-09-24

First Submitted that Met QC Criteria ⓘ

2023-10-01

First Posted ⓘ

2023-10-04

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2023-10-08

Last Update Posted ⓘ

2023-10-10

Last Verified ⓘ

2023-09

More Information

Terms related to this study

Keywords Provided by Simon Williamson Clinic

chemotherapy induced nausea and vomiting

NK-1

olanzapine

Additional Relevant MeSH Terms

Signs and Symptoms, Digestive

Nausea

Vomiting

Antiemetics

Autonomic Agents

Peripheral Nervous System Agents

Physiological Effects of Drugs

Gastrointestinal Agents

Antipsychotic Agents

Tranquilizing Agents

Central Nervous System Depressants

Psychotropic Drugs

Selective Serotonin Reuptake Inhibitors

Neurotransmitter Uptake Inhibitors

Membrane Transport Modulators

Molecular Mechanisms of Pharmacological Action

Neurotransmitter Agents

Serotonin Agents

Olanzapine

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

[HHS Vulnerability Disclosure](#)

Yes

Studies a U.S. FDA-Regulated Device Product

No

Product Manufactured in and Exported from the U.S.

No