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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.

Feedback

HELSINN EXHIBIT 2028
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00945

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/) related topics: Nausea and Vomiting (https://medlineplus.gov/nauseaandvomiting.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: 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)

FDA Drug and Device Resources (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

Name: Rudolph M Navari
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This study has 1 location

United States

Alabama Locations

Mount Olive, Alabama, United States, 35117
Recruiting
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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 • OLANZAPINE • Other Names: ◦ Olanzapine
Active Comparator: oLANZAPINE and Akynzeo to patients receiving highly emetogenic olANZAPINE plus Akynzeo	Drug: Akynzeo • OLANZAPINE • Other Names: ◦ 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

HHS Vulnerability Disclosure

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Product Manufactured in and Exported from the U.S.

No