A221701

Phase III Placebo-Controlled Trial to Evaluate Dexamethasone Use for Everolimus-Induced Oral Stomatitis: Prevention Versus Early Treatment Approaches: MIST (My Individualized Stomatitis Treatment)

ClinicalTrials.gov Identifier: NCT03839940

Study Background

Trial Description

This phase III trial studies how well dexamethasone works in reducing everolimus-induced oral stomatitis in patients with cancer. Dexamethasone may help to reduce the everolimus-induced oral stomatitis so as to improve quality of life in cancer patients.

Arms:

Group I (dexamethasone): (Experimental): Patients receive 10mg oral everolimus daily as standard of care and 10mL dexamethasone oral mouthwash, swished for 2-minutes daily, for 8 weeks.

Group II (placebo): (Placebo Comparator): Patients receive 10mg oral everolimus daily as standard of care and 10mL placebo oral mouthwash, swished for 2-minutes daily, for 8 weeks.

Objectives:

- PRIMARY OBJECTIVES:
  - I. To determine if the initiation of dexamethasone at the start of everolimus treatment prevents mTOR inhibitor-associated stomatitis (mIAS)-associated pain, compared to the initiation of placebo.
  - II. To determine if the initiation of dexamethasone at the start of everolimus treatment will be superior compared to the initiation of placebo in terms of the overall severity of mIAS-associated pain.
- SECONDARY OBJECTIVES:
  - I. To utilize the same measurement method that was reported in the SWISH trial: A combination of a patient reported pain scale, data from a normalcy of diet questionnaire, and clinician grading of stomatitis to determine the incidence of ≥ grade 2 mIAS.

  - II. To determine if the initiation of dexamethasone at the start of everolimus increases time to development of mouth pain using daily numerical analog scale patient-reported data collection.
  - III. To assess if quality of life is better when dexamethasone mouth rinse use starts at the same time as everolimus use versus at the time when mouth pain begins.
  - IV. To investigate if starting dexamethasone mouth rinse concurrent with starting everolimus improves patients' ability to adhere to everolimus therapy.
  - V. To compare dexamethasone prescription fill rates and timing between patients who received placebo versus study drug at the initiation of everolimus.
- Trial Design: OUTLINE: Patients are randomized to 1 of 2 groups.
  - GROUP I: Patients receive everolimus orally (PO) once daily (QD) as standard of care and dexamethasone as mouthwash over 2 minutes 4 times per day (QID) for 8 weeks.
  - GROUP II: Patients receive everolimus PO QD as standard of care and placebo as mouthwash over 2 minutes QID for 8 weeks.

Study Milestones:

Start date: February 15, 2019

Primary Completion Date: December 17, 2020

Publication Information:

Analysis Type: Primary

PubMed ID: 36693773

Citation: Semin Oncol. 2023 Jan 17;S0093-7754(23)00001-5.doi: 10.1053/j.seminoncol.2023.01.001. Online ahead of print.

Associated Datasets: NCT03839940-D1-Dataset.csv (analysis), NCT03839940-D2-Dataset.csv (tox)

Dataset Information:

Dataset Name: NCT03839940-D1-Dataset.csv (analysis)

Description: Dataset NCT03839940-D1-Dataset.csv (analysis) is one of 2 datasets associated with PubMed ID 36693773. This dataset contains data presented in Table 1, the analysis, and Figure 1.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT03839940-D1-Dataset.csv (analysis) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patient_id		
Arm	arm	A: Placebo, B: Dexamethasone	
Age (years)	age		
Cancer Type	cncrtype	Breast, Other	
Sex	genderdesc	Female, Male	
ECOG Performance Status	ecogpsbsl	0, 1, 2	
Evaluable for Co-Primary Endpoints	eval_coprim	No, Yes	
(If Unevaluable for Co-Primary Endpoints,) Reason	rsn	No Post-Baseline Pain Score Data, Other, Patient Withdrew Prior to Starting Treatment	
Patients Evaluable for Sensitivity Analyses where Baseline Pain Score Equals Zero	eval_sensitivity	No, Yes	
Patients Evaluable for Sensitivity Analyses Where at Least 50% of Post-Baseline Pain Reports Were Given	eval50	No, Yes	
Patients Evaluable for Sensitivity Analyses Where at Least 80% of Post-Baseline Pain Reports Were Given	eval80	No, Yes	
Evaluable for AE Analyses	evalae	No, Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Was Dexamethasone Script Filled Based on Weekly Phone Calls with Nurses (Only For Patients Evaluable for Co-Primary Endpoints)	dex_filled	No, Yes	
Number of NAMPS Forms with At Least One Pain Score Provided (Only For Patients Evaluable for Co-Primary Endpoints)	namps_submitted	2, 4, 5, 6, 7, 8, 9	
Mouth Pain Experienced	mouth_pain	No, Yes	
AUC Values	auc_y		
Mouth Sores Experienced	mouth_sores	No, Yes	
Greater Than or Equal to Grade 2 mTOR Inhibitor-Associated Stomatitis Experienced	mias_incidence	No, Yes	
Whole Blood Everolimus Concentrations (ng/mL)	MEAN_EV24		