COG-ACCL2531: A Randomized Double-Blinded Trial of Xylitol Dental Wipes for the Prophylaxis of Bloodstream Infections from Oral Organisms in Pediatric Patients with Acute Myeloid Leukemia

FAST FACTS
Eligibility Reviewed and Verified By
_____ MD/DO/RN/LPN/CRA Date _____
_____ MD/DO/RN/LPN/CRA Date _____
Consent Version Dated_____

PATIENT ELIGIBILITY:
Important note: The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01). All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient's medical research record which will serve as the source document for verification at the time of audit.

The CIRB has determined that assent of children age ___ and older is a necessary condition for proceeding with the research.

INCLUSION CRITERIA:
1. Patient must be ≥ 1 year to ≤ 25 years old at enrollment. 3
2. Diagnosis Patient must have a diagnosis of AML according to the 2016 World Health Organization classification with or without extramedullary disease. Patients with either newly diagnosed or relapsed AML are eligible as long as they meet the planned treatment criteria (Section 3.2.3).
3. Planned Treatment Patient should be planned to receive at least 2 consecutive cycles of myelosuppressive chemotherapy. Each cycle must: • Contain IV cytarabine (liposomal formulations allowed), and • The duration of severe neutropenia should be expected to be ≥ 7 days.
4. Minimum of one visible or erupted tooth '
5. Agree to avoid xylitol containing gum or toothpaste during intervention period

HSCT conditioning cannot count as one of the two required planned cycles.

EXCLUSION CRITERA:
1. Patients with Down syndrome-associated AML
2. Prior Therapy: Prior radiation treatment for cancer of oral cavity, head or neck in past 6 months per study participant's medical record 3.2.7 Patients with known history of allergy to xylitol.
3. Patients with known history of allergy to grapes or grape flavoring.
4. Patients who are actively being treated for an oral organism related blood stream infection (see Appendix III for list)
5. Patients for whom the practitioner believes are unable to comply with use of oral dental wipes.

Please see Section 4.5 for the concomitant therapy restrictions for patients during treatment.

TREATMENT PLAN:
At the time of enrollment patients will be randomized to receive either xylitol dental wipes or control dental wipes (see Section 3.1.6).

The treatment period (the period when study therapy is administered) begins within 5 days of the start of an AML chemotherapy cycle and continues for each cycle until ANC ≥ 100/μL at least once following nadir or 30 days from the initiation of wipes, whichever occurs first (for each of the duration of two cycles total). Study therapy will start between Day 1 and Day 5 of the subsequent chemotherapy cycle and continue until ANC ≥ 100/μL at least once following the nadir or for a maximum of 30 consecutive days for the cycle.

REQUIRED OBSERVATIONS:

All baseline studies must be performed prior to starting protocol therapy. All subsequent observations can be obtained +/- 2 days of the date specified below.

STUDIES TO BE OBTAINED	Baseline[1]	Infection Observation Period[2]	Cycle 1	Cycle 2
History, Demographic & Clinical Information[3]	X			
Performance Status[4]	X			
Dental Assessment[5]	X		-	Day 1
Oral Mucositis Assessment (ChIMES)[6]	X		Day 14	Day 14
Oral Mucositis (CTCAE)	X		X	X
Infection Information[7]		X		
Blood culture[7]		X		

[1] Baseline assessment will take place of Day 0-5 of first cycle of chemotherapy on study prior to wipe initiation.
[2] See Section 7.1.2 for Infection Observation Period details.
[3] See Section 7.1.1 for History, Demographic & Clinical Information details.
[4] Refer to APPENDIX IV: Performance Status Scales/Scores
[5] Refer to APPENDIX V: Oral Health Assessment Tool: American Academy of Pediatrics Oral Health Assessment. This tool is to be used for clinical guidance and reference for dental caries and oral health status.
[6] Limited to English speaking patients/families (ChIMES is only available in English). Two versions of the tool are available; use the Child version for patients ≥ 12 years old and the Parent version for patients < 12 years old. See the protocol webpage for the ChIMES documents.
[7] Obtained as consistent with good patient care.

This listing only includes evaluations necessary to answer the study aims. Obtain other studies as necessary for good clinical care.

BIOLOGY REQUIREMENTS:

See Section 13.0 for details on timing of collection, specimen requirements, and shipment information.

Specimen: Saliva	Baseline	Cycle 1		Cycle 2	
Oral Microbiome[1]	X	Day 14	Upon neutrophil recovery to ≥ 100/µL	Day 1	Upon neutrophil recovery to ≥ 100/µL

[1]All observations for optional studies will have a +/- 5 -day window.

EXPERIMENTAL DESIGN SCHEMA