

Clinical Trial CT-2017-CTN-05069-1 v1 Repository

Submission Date: 08/01/2018
Acknowledged by TGA

Application

Sponsor Name School of Dentistry, The University of Queensland
Sponsor Address UQ Oral Health Centre corner Bramston Terrace and Herston Road Herston QLD 4006
Notification Fee \$350

Trial Details

Contact Name Nebu Philip
Contact Phone Number 0452355711
Contact Email n.philip@uq.edu.au
Protocol Number 05069
Expected Trial Start Date 01/06/2018
Expected Completion Date 31/12/2018
Potential Use of Restricted Goods No
Title of Study Ecological approaches to dental caries prevention: A controlled trial to evaluate the influence of CPP-ACP - Cranberry toothpastes in effecting an ecological change in the oral plaque microbiome
Trial Type Phase 1, Device
Trial Type Description (if necessary) This research project aims to evaluate whether the microbial ecology of dental plaque biofilms can be altered by toothpastes containing either Casein Phosphopetide-Amorphous Calcium Phosphate (CPP-ACP) or a combination of CPP-ACP and cranberry.
Total Number of Patients to be Enrolled in Trial 51-200
Therapeutic Area Other
This Trial Involves the use of a Medical Device
Is comparator controlled

Devices

Product Name	Is this a kit?	Manufacturer	GMDN	Description	Intended Purpose	Other Description
CPP-ACP toothpaste (MI Paste ONE)	Single Device	GC Australasia Dental Pty Ltd	Dental material, desensitizing resin (45232)		Investigational Product	
CPP-ACP - Cranberry toothpaste ('All-in-one')	Single Device	GC Australasia Dental Pty Ltd		A CPP-ACP toothpaste enriched with a cranberry additive. Highly purified organic cranberry extract (250-500µg/ml) is added to the MI Paste One CPP-ACP toothpaste to enhance its antimicrobial effects against cariogenic bacteria responsible for tooth decay. Cranberry has been shown to inhibit bacterial synthesis of insoluble glucans responsible for establishing a cariogenic oral plaque biofilm. The 'All-in-one' CPP-ACP - Cranberry toothpaste is intended to be used for routine twice-daily tooth brushing. Product category: Medical Device Class 1	Investigational Product	
Standard fluoride toothpaste	Single Device	GC Australasia Dental Pty Ltd		A toothpaste that is similar to the two investigational toothpastes in all aspects (including its 1100ppm fluoride concentration), except it does not contain either CPP-ACP or cranberry, is proposed to be used as the comparator representing standard oral care therapy.	Comparator	

Sites

Site	Site Address, Location	Expected Site Start Date	Principal Investigator Name	Principal Investigator Contact Phone Number	Principal Investigator Contact Email	HREC Name, Code	HREC Contact Officer, Position	HREC Contact Phone	HREC Contact Email	Approving Authority Name	Approving Authority Contact Officer, Position	Contact Phone	Contact Email
UQ Oral Health Centre	Herston, Brisbane, QLD	01/06/2018	Nebu Philip	0452355711	n.philip@uq.edu.au	The Prince Charles Hospital Human Research Ethics, EC00168	Anne Carle, HREC Coordinator and Manager	0731394500	ResearchTPCH@health.qld.gov.au	Metro North Hospital and Health Service	Jacqueline Robinson, Research Governance Officer	0736468579	RBWH-RGO@health.qld.gov.au

Change to Trial Details

Completion