TCTR ID : TCTR20230427005

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date :	20 April 2023
First Posted Date :	27 April 2023
Last Update Posted Date :	30 June 2024

Title

Public Title :	Clinical, Patient-Reported outcomes and Efficacy of Static Computer-Assisted Sinus Floor Augmentation: A Randomized Controlled Trial
Acronym :	SCA-SFA
Scientific Title :	Clinical, Patient-Reported outcomes and Efficacy of Static Computer-Assisted Sinus Floor Augmentation: A Randomized Controlled Trial.
Sponsor ID/ IRB ID/ EC ID :	HREC-DCU 2022-103
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20230427005
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	HREC-DCU 2022-103
Date of Approval :	10 February 2023
Board Name :	Human Research Ethics Committee
Board Affiliation :	Faculty of Dentistry, Chulalongkorn University
Board Contact :	Business Phone : 022188866 Ext. No Data
	Business Email : ethics.dent.chula@gmail.com
	Business Address : 34 Henri Dunant Roas , Wang Mai , Pathumwan , Bangkok ,10330

Sponsor

Source(s) of Monetary or Material Supports :	OSS HYDROXY COMPANY LIMITED
Study Primary Sponsor :	Chulalongkorn University
Responsible Party :	Name/Official Title : Faculty of Dentistry, Chulalongkorn University
	Organization : Chulalongkorn University
	Phone : 022188635 Ext. No Data
	Email : cudentpr@gmail.com
Study Secondary Sponsor :	the 90th Anniversary of Chulalongkorn University Scholarship, Ratchadapisek Somphot Fund

Protocol Synopsis

Protocol Synopsis :	The recent development of s-CAIS has the potential to improve clinical and patient reported outcomes of sinus surgery by increasing precision, minimizing complications and risks and reducing surgery duration. Nevertheless, there is at present no research systematically assessing the potential and limitations of s-CAIS for sinus augmentation surgery in particularly when compared with conventional freehand technique. The aim of this study is to investigate the clinical and patient-reported outcomes as well as efficacy of s-CAIS in sinus augmentation surgery, as compared to the conventional freehand approach

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Patients who need for implant placement in posterior maxilla with residual alveolar bone height between 1-5 mm
Keywords :	Surgical guide, Guided surgery, computer-assisted surgery, lateral window sinus floor elevation, sinus augmentation, patient-reported outcomes

Eligibility

Inclusion Criteria :	1.Medically healthy adult (ASA I-II) and age more than 21 years old 2.Non-smoker or previous smoker (quit more than 5 years) or light smoker with less than 10 cigarettes/day 3.Edentulous spaces in posterior maxilla in 1 or 2 posterior quadrants with an alveolar bone defect which requires lateral approach sinus floor augmentation for 1-3 implant placement (residual crestal height less than 6 mm) 4.Absence of sinus membrane pathology or rhinosinusitis or other pathology requiring management
Gender :	Both
Age Limit :	Minimum : 21 Years Maximum : N/A (No limit)
Exclusion Criteria :	1. Medically compromised subjects (ASA III-V) 2.General contraindications against implant treatment or augmentative procedures (immunodeficiency or advanced systemic diseases or corticosteroid medication) 3.Patients taking oral bisphosphonates longer than 5 years /anti-angiogenic/RANKL inhibitor medications or receiving local radiotherapy 4.Heavy smoker or previous heavy smoker (quit less than 5 years or more than 10 cigarettes/day) 5.Acute/Chronic unmanaged symptomatic sinusitis 6.Type 1 implant placement (immediate implant placement following extraction) 7.Need for simultaneous soft tissue augmentation. 8.Residual bone height more than 6 mm 9.Subjects aged less than 21 years old
Accept Healthy Volunteers :	Yes

Status

Overall Recruitment Status :	Completed	
Key Trial Dates	Study Start Date (First enrollment) : 01 May 2023	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 29 February 2024	Indicate Type : Actual
	Study Completion Date : 31 March 2024	Indicate Type : Actual

Design

Study Type :	Interventional
Primary Purpose :	Treatment
Study Phase :	Phase 2
Intervention Model :	Parallel
Number of Arms :	2
Masking :	Masked Masked Role : Allocation concealment, Outcome Assessor, Statistician
Allocation :	Randomized
Control :	Placebo
Study Endpoint Classification :	Efficacy Study
Sample size	
	Planned sample size : 40
	Actual sample size at study completion : 40
Intervantion Arm 1	
	Intervention name : surgical guide
	Intervention Type : Experimental
	Intervention Classification : Device
	Intervention Description : Placement the device to perform osteotomy outline into maxillary sinus
Intervantion Arm 2	
	Intervention name : freehand surgery
	Intervention Type : No Intervention
	Intervention Classification : No treatment
	Intervention Description : Define osteotomy outline to maxillary sinus with conventional freehand

Outcome

Primary Outcome

1. Outcome Name : Patient-reported Outcomes
Metric / Method of measurement : Visual analog Scale Scores
Time point : day1-7,14 after surgery
2. Outcome Name : Complications, surgical wound healing
Metric / Method of measurement : Dichotomic score
Time point : intraoperative , 2,4 weeks after surgery
3. Outcome Name : Duration of surgery
Metric / Method of measurement : Time
Time point : Intraoperation

Secondary Outcome

1. Outcome Name : Operator's opinion
Metric / Method of measurement : Linkert scale
Time point : Intraoperation

Location

Section A : Central Contact

Central Contact	First Name : Nattakarn	Middle Name :	Last Name : Narongchai
	Degree : DDS	Phone : 0909896936 Ext. : No Data	Email : n_wan39@hotmail.com
Central Contact Backup	First Name : Sureeporn	Middle Name :	Lastname : Tantisak
	Degree :	Phone : 022188866 Ext. : No Data	Email : ethics.dent.chula@gmail.com

Section B Facility Information and Contact

1. Site Name : Department of oral and Maxillofacial Surgery , Faculty of Dentistry, Chulalongkorn University

	City : Pathumwan	State/Province : Bangkok	Postal Code : 10330
	Country : Thailand	Recruitment Status : Pending (Not yet recruiting)	
Facility Contact	First Name : Nattakarn	Middle Name :	Last Name : Narongchai
	Degree : DDS	Phone : 0909896936 Ext. : No Data	Email : n_wan39@hotmail.com
Facility Contact Backup	First Name : Atiphan	Middle Name :	Last Name : Pimkhaokham
	Degree : DDS,PhD,MPA,BPA	Phone : 0891308046 Ext. : No Data	Email : Atiphan.P@chula.ac.th
Investigator Name	First Name : Nikos	Middle Name :	Last Name : Mattheos
	Degree : DDS,Msc,PhD	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Nattakarn	Middle Name :	Last Name : Narongchai
Degree : DDS	Phone : 0909896936 Ext. : No Data	Email : n_wan39@hotmail.com
Postal Address : Office of Research Affairs 10th floor Somdejya 93 Building Faculty of Dentistry Chulalongkorn University		
State/Province : Bangkok	Postal Code : 10330	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Dentistry , Chulalongkorn University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Nattakarn	Middle Name :	Last Name : Narongchai
Degree : DDS	Phone : 0909896936 Ext. : No Data	Email : n_wan39@hotmail.com
Postal Address : Office of Research Affairs 10th floor Somdejya 93 Building Faculty of Dentistry Chulalongkorn University		
State/Province : Bangkok	Postal Code : 10330	
Country : Thailand	Official Role : Study Chair	
Organization Affiliation : Human Research Ethics Committee Faculty of dentistry Chulalongkorn University		

Summary Results

Date of posting of results summaries : 20 June 2024
Date of first journal publication of results : Not yet published

Baseline Characteristics :	A total of 40 patients were enrolled and operated (20 SFA group and 20 SCA-SFA group). No significant differences were found in patient demographic characteristics, site anatomy, procedure type, as well as extent of incisions and flap design between the two treatment groups
Participant Flow :	40 patients underwent lateral sinus augmentation (20 freehand-SFA + 20 SCA-SFA). Patient-reported outcomes were recorded in Visual Analog Scale (VAS) on days 1-7, 14 and intra- and post-operative complications were recorded on week 2,4 after surgery. Operation time and operator's assessment of efficacy for SCA-SFA utility were recorded.
Adverse events :	No adverse events
Outcome Measures :	Primary outcomes 1.Patient-Reported Outcomes (PRO) using Visual Analogue Scales (VAS) 0 -10 : - wound healing (bleeding, swelling, pain, bruising) - discomfort of the sinuses (nosebleeds, nasal congestion, rhinorrhea, hyposmia) 2. Daily consumption (yes/no % number of tablets) of analgesics. 3. Clinical recordings of intra-operative (membrane perforation, excessive bleeding, root exposure, flap tearing) and post-operative complications at week 2,4 (flap dehiscence, pain/sensitivity on palpation, swelling / obliteration of sulcus, maxillary sinusitis, suppuration/purulent discharge, paresthesia, loss of augmentation, pathological fractures, sequestrum) 4. Duration of specific procedures and overall surgery
Brief Summary of Results :	No statistically significant difference was found between the two groups with regards to PROMs and intra-, post-operative complications, apart from higher level of swelling for SCA-SFA patients on day 2 after surgery. The use of SCA-SFA significantly reduced the time needed to conduct the window osteotomy (SCA 1113.80 + 730.41 sec vs SCA-SFA 685.50 + 285.28 sec) and the total surgery duration (SCA 4193.30 + 1204.98 sec vs SCA-SFA 3374.35 + 960.45 sec).

Deidentified Individual Participant-level Data Sharing

Plan to share IPD :	No
Reason :	Prohibited from regulations/contracts), Fear of inappropriate use of data, Need a consensus from colleagues, Personal reasons

Publication from this study

MEDLINE Identifier :	No Data
URL link to full text publication :	No Data