TCTR ID : TCTR20181008003

OTHER ID :

Overall Recruitment Status : Recruiting

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date :	06 October 2018
First Posted Date :	08 October 2018
Last Update Posted Date :	08 October 2018

Title

Public Title :	A multicenter clinical trial pilot study of Radial head prosthesis fabricated by 3D printing technique
Acronym :	No Data
Scientific Title :	A multicenter clinical trial pilot study of Radial head prosthesis fabricated by 3D printing technique
Sponsor ID/ IRB ID/ EC ID :	291/61
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20181008003
Secondary ID :	728/2018

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	291/61
Date of Approval :	No Data
Board Name :	Institutional Review Board Faculty of Medicine, Chulalongkorn University
Board Affiliation :	Faculty of Medicine, Chulalongkorn University
Board Contact :	Business Phone : 022564493 Ext. No Data
	Business Email : No Data
	Business Address : Institutional Review Board Faculty of Medicine, Chulalongkorn University Rama4Road Pathumwan Bangkok 10330

Sponsor

Source(s) of Monetary or Material Supports :	Meticuly Company Limited
Study Primary Sponsor :	Meticuly Company Limited
Responsible Party :	Name/Official Title : Meticuly Company Limited
	Organization : Meticuly Company Limited
	Phone : 020249602 Ext. No Data
	Email : info@meticuly.com
Study Secondary Sponsor :	Meticuly Company Limited

Protocol Synopsis

Protocol Synopsis : Up to now, there are no patient specific instrument of radial head available in Thailand. Our pilot studyâ€™s aim is to design and create a radial head prosthesis fabricated by 3D printing.

Research objective : To assess safety and efficacy of radial head prosthesis fabricated by 3D printing technique in trauma patients and patients with tumor who required resection of radial head in King Chulalongkorn Memorial Hospital (KCMH).

Primary question : Is it safe to use a radial head prosthesis fabricated by 3D printing technique in trauma patients and patients with tumor who required resection of radial head?

Secondary question : Is a radial head prosthesis fabricated by 3D printing have a good efficacy for trauma patients and patients with tumor who required resection of radial head?

Study design : Medical Device Clinical Trial : Pilot StudyThe elbow joint is a complex joint, which, when impaired in function, leads to severe disability. In some cases however, an arthroplasty might be an appropriate treatment. The radial head is an important secondary stabilizer of the elbow. Replacement of the radial head is recommended in cases in which the injury of the ligaments requires a secondary stabilizer, and

it is not possible to reconstruct the radial head. Up to now, there are no patient specific instrument of radial head available in Thailand. Our pilot studyâ€™s aim is to design and create a radial head prosthesis fabricated by 3D printing.

After performing the surgery, the data will be recored from each follow up visit at 1st, 6th, 12th, 24th, 36th and 48th week.

Primary and Secondary outcome
Complication
- Elbow subluxation/dislocation
- Stem loosening
- Implant fracture
- Infection
- Hypersensitivity reaction
- Radiolucent lines
- Heterotrophic ossification

CBC, BUN, Cr, Electrolyte, LFT, PT, PTT, INR, ESR, CRP, UA and Serum aluminum at 12th and 48th week.

- DASH score
- Mayo Elbow Performance Score
- Pain Visual Analog Scale
- Range of Motion
- Congruity of the radiocapitellar and ulnohumeral joints

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Radial head fracture
Keywords :	Radial head fracture 3d printing radial head prosthesis

Eligibility

Inclusion Criteria :	Age 18-80 years old Radial head fracture Mason type III-IV Radial head tumor not beyond 8 cm from radial head Normal opposite radial head with no history of surgery or fracture Willing to join the research
Gender :	Both
Age Limit :	Minimum : 18 Years Maximum : 80 Years
Exclusion Criteria :	Osteoarthritis of elbow Patients with infection Unconscious patient or Mental illness patients
Accept Healthy Volunteers :	No

Status

Overall Recruitment Status :	Recruiting	
Key Trial Dates	Study Start Date (First enrollment) : 06 October 2018	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 01 November 2018	Indicate Type : Anticipated
	Study Completion Date : 06 October 2019	Indicate Type : Anticipated

Design

Study Type :	Interventional
Primary Purpose :	Treatment
Study Phase :	Phase 1/Phase 2
Intervention Model :	Single arm
Number of Arms :	1
Masking :	Open Label
Allocation :	N/A

Control : N/A

Study Endpoint Classification : Safety Study

Sample size

Planned sample size : 10

Intervantion Arm 1

Intervention name : Radial head prosthesis fabricated by 3D printing technique

Intervention Type : Experimental

Intervention Classification : Procedure/Surgery

Intervention Description : Radial head prosthesis fabricated by 3D printing technique design by the normal radial head from contralateral side made by RematitanÂ® CL, Ti90 Al6 V4, using Selective Laser Melting technique and Autoclave

Outcome

Primary Outcome

1. Outcome Name : Complication

Metric / Method of measurement : Elbow subluxation/dislocation, Stem loosening, Implant fracture, Infection, Hyp

Time point : 1st, 6th, 12th, 24th, 36th, and 48th weeks after surgery

Secondary Outcome

1. Outcome Name : Function

Metric / Method of measurement : DASH score, Mayo Elbow Performance Score, Pain Visual Analog Scale, Range of Motion, Congruity of th

Time point : 1st, 6th, 12th, 24th, 36th, and 48th weeks after surgery

Location

Section A : Central Contact

Central Contact	First Name : Chris	Middle Name :	Last Name : Charoenlap
	Degree :	Phone : 081-4819209 Ext. : No Data	Email : chris.cha@chula.ac.th
Central Contact Backup	First Name : Nonn	Middle Name :	Lastname : Jaruthien
	Degree :	Phone : 089-6656655 Ext. : No Data	Email : nonnjaru@gmail.com

Section B Facility Information and Contact

1. Site Name : Faculty of medicine, Chulalobgkorn university

	City : Pathumwan	State/Province : Bangkok	Postal Code : 10330
	Country : Thailand	Recruitment Status : Recruiting	
Facility Contact	First Name : Chris	Middle Name :	Last Name : Charoenlap
	Degree :	Phone : 081-4819209 Ext. : No Data	Email : chris.cha@chula.ac.th
Facility Contact Backup	First Name : Nonn	Middle Name :	Last Name : Jaruthien
	Degree :	Phone : 089-6656655 Ext. : No Data	Email : nonnjaru@gmail.com
Investigator Name	First Name :	Middle Name :	Last Name :
	Degree :	Role :	

Section C : Contact for Public Queries (Responsible Person)

First Name : Chris	Middle Name :	Last Name : Charoenlap
Degree : No Data	Phone : 081-4819209 Ext. : No Data	Email : chris.cha@chula.ac.th
Postal Address : Faculty of medicine, Chulalobgkorn university		
State/Province : Bangkok	Postal Code : 10330	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Chulalongkorn University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Chris	Middle Name :	Last Name : Charoenlap
Degree : No Data	Phone : 081-4819209 Ext. : No Data	Email : chris.cha@chula.ac.th
Postal Address : Faculty of medicine, Chulalobgkorn university		
State/Province : Bangkok	Postal Code : 10330	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Chulalongkorn University		

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No Data

Plan description : No Data

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data