

**TCTR ID : TCTR20181008003**

Overall Recruitment Status : Recruiting

**OTHER ID :**

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

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**Tracking Information**

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

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**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

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**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

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**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

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**Protocol Synopsis**

Protocol Synopsis : Up to now, there are no patient specific instrument of radial head available in Thailand. Our pilot study'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 Study  
The 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 study'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**

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#### Health Conditions

Health Condition(s) or Problem(s) Studied : Radial head fracture

Keywords : Radial head fracture 3d printing radial head prosthesis

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#### 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

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#### 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

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#### 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

Intervention 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

<b>Facility Contact</b>	First Name : Chris	Middle Name :	Last Name : Charoenlap
	Degree :	Phone : 081-4819209 Ext. : No Data	Email : chris.cha@chula.ac.th

<b>Facility Contact Backup</b>	First Name : Nonn	Middle Name :	Last Name : Jaruthien
	Degree :	Phone : 089-6656655 Ext. : No Data	Email : nonnjaru@gmail.com

<b>Investigator Name</b>	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

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**Publication from this study**

MEDLINE Identifier : No Data

URL link to full text publication : No Data

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