

TCTR ID : TCTR20210922002

Overall Recruitment Status : Pending (Not yet recruiting)

OTHER ID :

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

Tracking Information

First Submitted Date : 21 September 2021
First Posted Date : 22 September 2021
Last Update Posted Date : 21 September 2021

Title

Public Title : Oxford phase 3 unicompartmental knee arthroplasty in Thailand: Distribution of prosthetic size and height based on gender distribution of femoral component size
Acronym : No Data
Scientific Title : Oxford phase 3 unicompartmental knee arthroplasty in Thailand: Distribution of prosthetic size and height based on gender distribution of femoral component size
Sponsor ID/ IRB ID/ EC ID : 728/2564(IRB4)
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20210922002>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : 722/2021
Date of Approval : 18 September 2021
Board Name : Siriraj Institutional Review Board
Board Affiliation : Mahidol university, Thailand
Board Contact : Business Phone : 024192667 Ext. No Data
Business Email : siethics@mahidol.ac.th
Business Address : Human Research Protection Unit, Faculty of Medicine Siriraj Hospital, Mahidol University His Majesty the King's 80th Birthday Anniversary 5th December 2007 Building 2nd floor Room 210 2 Wang Lang Road Bangkoknoi, Bangkok 10700, Thailand

Sponsor

Source(s) of Monetary or Material Supports : none
Study Primary Sponsor : none
Responsible Party : Name/Official Title : Assoc.Prof. Chaturong Pornrattanamaneewong
Organization : Mahidol university
Phone : 0817553977 Ext. No Data
Email : toonchaturong@gmail.com
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : The distribution of Oxford phase 3 unicompartmental knee arthroplasty (OUKA) prosthetic size and guidelines to determine the ideal femoral component (Fc) size have been mainly studied in Western population. We therefore aim to investigate the distribution of OUKA prosthetic size, and the influencing factors for selecting the Fc size in Thai patients.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : The distribution of Oxford phase 3 unicompartmental knee arthroplasty prosthetic size, and the influencing factors for selecting the femoral component size in Thai patients with medial osteoarthritic knees
Keywords : Unicompartmental knee arthroplasty Distribution of prosthesis Femoral component size

Eligibility

Inclusion Criteria : Between 2003 and 2019, the patients who underwent the OUKA phase 3 in our institute were included.

Gender : Both

Age Limit : Minimum : 18 Years Maximum : N/A (No limit)

Exclusion Criteria : Incomplete data

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Pending (Not yet recruiting)

Key Trial Dates Study Start Date (First enrollment) : 27 September 2021 Indicate Type : Anticipated

Completion Date (Last subject, Last visit) : 10 October 2021 Indicate Type : Anticipated

Study Completion Date : 31 October 2021 Indicate Type : Anticipated

Design

Study Type : Observational

Primary Purpose : Other

Number of Groups : 5

Study Endpoint Classification : N/A

Sample size

Planned sample size : 700

Actual sample size at study completion :

Observation Group 1

Group name : XS-sized femoral component

Group Description : The patients who used the extra-small sized femoral component

Observation Group 2

Group name : S-sized femoral component

Group Description : The patients who used the small sized femoral component

Observation Group 3

Group name : M-sized femoral component

Group Description : The patients who used the medium sized femoral component

Observation Group 4

Group name : L-sized femoral component

Group Description : The patients who used the large sized femoral component

Observation Group 5

Group name : XL-sized femoral component

Group Description : The patients who used the extra-large sized femoral component

Outcome

Primary Outcome

1. Outcome Name : Distribution of prosthetic size

Metric / Method of measurement : Number of each prosthetic size used

Time point : During the operation

Secondary Outcome

1. Outcome Name : none

Metric / Method of measurement : none

Time point : none

Location

Section A : Central Contact

Central Contact First Name : Chaturong

Middle Name :

Last Name : Pornrattanamaneeewong

Degree : MD

Phone : 0817553977 Ext. : No Data

Email : toonchaturong@gmail.com

Central Contact Backup First Name : Rapeepat

Middle Name :

Lastname : Narkbunnam

Degree : MD

Phone : 0819351669 Ext. : No Data

Email : mai_parma@hotmail.com

Section B Facility Information and Contact

1. Site Name : Siriraj hospital, Mahidol university

City : Bangkok

State/Province : Bangkok

Postal Code : 10700

Country : Thailand

Recruitment Status : Pending (Not yet recruiting)

Facility Contact First Name : Chaturong

Middle Name :

Last Name : Pornrattanamaneewong

Degree : MD

Phone : 0817553977 Ext. : No Data

Email : toonchaturong@gmail.com

Facility Contact Backup First Name : Rapeepat

Middle Name :

Last Name : Narkbunnam

Degree : MD

Phone : 0819351669 Ext. : No Data

Email : mai_parma@hotmail.com

Investigator Name First Name : Chaturong

Middle Name :

Last Name : Pornrattanamaneewong

Degree : MD

Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Chaturong

Middle Name :

Last Name : Pornrattanamaneewong

Degree : MD

Phone : 0817553977 Ext. : No Data

Email : toonchaturong@gmail.com

Postal Address : Department of Orthopedic Surgery, Siriraj hospital, 2 Prannok road

State/Province : Bangkok

Postal Code : 10700

Country : Thailand

Official Role : Study Principal Investigator

Organization Affiliation : Mahidol university

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Chaturong

Middle Name :

Last Name : Pornrattanamaneewong

Degree : MD

Phone : 0817553977 Ext. : No Data

Email : toonchaturong@gmail.com

Postal Address : Department of Orthopedic Surgery, Siriraj hospital, 2 Prannok road

State/Province : Bangkok

Postal Code : 10700

Country : Thailand

Official Role : Study Principal Investigator

Organization Affiliation : Mahidol university

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : The patients ' confidentiality

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data
