

TCTR ID : TCTR20190115001

Overall Recruitment Status : Enrolling by invitation

OTHER ID :

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

Tracking Information

First Submitted Date : 15 January 2019
First Posted Date : 15 January 2019
Last Update Posted Date : 15 January 2019

Title

Public Title : Establishment of Siriraj Integrated perioperative geriatric research network
Acronym : No Data
Scientific Title : Establishment of Siriraj Integrated perioperative geriatric research network
Sponsor ID/ IRB ID/ EC ID : Si 515/2017
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20190115001>
Secondary ID : -

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : Si 515/2017
Date of Approval : No Data
Board Name : Siriraj Institutional Review Board
Board Affiliation :
Board Contact : Business Phone : 024192667 Ext. 72
Business Email : arunotai.sir@mahodol.ac.th
Business Address : 2 Wang Lang Rd. Bangkoknoi Bangkok 10700

Sponsor

Source(s) of Monetary or Material Supports : department of Anesthesiology
Study Primary Sponsor : Faculty of Medicine Siriraj Hospital Mahidol University
Responsible Party : Name/Official Title : Siriraj Integrated perioperative geriatric excellent research center
Organization : Faculty of Medicine Siriraj Hospital Mahidol University
Phone : 024192904 Ext. -
Email : arunotai.sir@mahidol.ac.th
Study Secondary Sponsor : Faculty of Medicine Siriraj Hospital Mahidol University

Protocol Synopsis

Protocol Synopsis : The guidelines on the care for elderly patients who receive anesthesia at Siriraj Hospital are currently unclear for comprehensive elderly care. Due to the different methods for diagnosis and treatment from different medical fields, there is a lack of a shared system, a multi-disciplinary team and practical guidelines to approach patients, which can negatively affect patient safety. The treatment results may not be as effective and the cost of patient care may increase. The multidisciplinary care team of the elderly patients has cooperated with each other in order to identify the problem and find the best solution to handle it through a multi-disciplinary guideline. When there is a difference of opinion among the research team, research studies will be carried out in order to act as an important driving force in knowledge management and service development according to evidence-based practice. Over the past year, the Integrated perioperative geriatric research network has constantly organized a brainstorming session by a multi-disciplinary team in order to define the real problems of patient care by expanding research topics in order to bridge the knowledge gap. The main focus is to conduct quality research studies to improve the service, share the knowledge and promote the application of the principles within Siriraj Hospital and across Thailand. The research network is currently conducting research on 5 different subjects, 3 of which are sponsored by type 4 grant. The total number of patients joining the project over the past 3 years is 1,350. All the 5 research studies focus mainly on the prevention and treatment of complications. However, the plan to treat long-term patients has not been created. The research network plans to follow up elderly patients for at least 3 months to 1 year (cohort study) to monitor cognitive function about cognitive change after anesthesia. This issue is the main concern of patients and their families. There has never been a systematic study

prevalence of cognitive function in Thailand and how it affects patients and society. The research network is also working on improving life quality and studying long-term complications, which can have an impact on patients, families and society.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : number follow up 3 months and 1 year money

Keywords : No Data

Eligibility

Inclusion Criteria : 1. Patients over age 70 years
2. Patients come to undergo surgery and anesthesia by general anesthesia (GA), regional anesthesia (RA) combined GA and RA
3. Patients underwent medium and large size surgery.

Gender : Both

Age Limit : Minimum : 70 Years Maximum : 100 Years

Exclusion Criteria : 1. Don't Informed consent
2. Can't communicate in Thai language
3. Plan to refer treatment to another hospital after surgery
4. Neuromuscular disease

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Enrolling by invitation

Key Trial Dates	Study Start Date (First enrollment) : 06 December 2017	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 27 December 2018	Indicate Type : Anticipated
	Study Completion Date : 07 December 2020	Indicate Type : Anticipated

Design

Study Type : Observational

Primary Purpose : Screening

Number of Groups : 1

Study Endpoint Classification : N/A

Sample size

Planned sample size : 900

Actual sample size at study completion :

Observation Group 1

Group name : POCD in elderly patients

Group Description : Older patients in particular are vulnerable to memory disturbances and other types of cognitive impairment after surgical operations. Patients over age 60 had postoperative cognitive dysfunction (POCD) three months after surgery. This is an important issue in perioperative care as extensive surgery on older patients becomes more common.

Outcome

Primary Outcome

1. Outcome Name : Incidence of postoperative cognitive dysfunction (POCD) in elderly patients

Metric / Method of measurement : Montreal cognitive assessment (MOCA)

Time point : 3 months

Secondary Outcome

1. Outcome Name : Quality of life in elderly patients

Metric / Method of measurement : EQ5D5L

Time point : 3 months

Location**Section A : Central Contact**

Central Contact	First Name : Arunotai	Middle Name :	Last Name : Siriussawakul
	Degree :	Phone : 02- 4197990 Ext. : No Data	Email : arunotai.sir@mahidol.ac.th
Central Contact Backup	First Name : Wasumadee	Middle Name :	Lastname : Ko-amornsup
	Degree :	Phone : 086-7806632 Ext. : No Data	Email : Chompoo.wkm@gmail.com

Section B Facility Information and Contact

1. Site Name : Arunotai Siriussawakul

City : No Data	State/Province :	Postal Code :
Country : Thailand	Recruitment Status : Enrolling by invitation	

Facility Contact	First Name : Arunotai	Middle Name :	Last Name : Siriussawakul
	Degree :	Phone : 02- 4197990 Ext. : No Data	Email : arunotai.sir@mahidol.ac.th

Facility Contact Backup	First Name : Wasumadee	Middle Name :	Last Name : Ko-amornsup
	Degree :	Phone : 086-7806632 Ext. : No Data	Email : Chompoo.wkm@gmail.com

Investigator Name	First Name : Arunotai	Middle Name :	Last Name : Siriussawakul
	Degree :	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Arunotai	Middle Name :	Last Name : Siriussawakul
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Postal Address : 2 WANG LANG Rd. BANGKOKNOI		
State/Province : Bangkok	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine Siriraj Hospital. Mahidol University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Arunotai	Middle Name :	Last Name : Siriussawakul
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Postal Address : 2 Wang Lang Rd. Bangkoknoi		
State/Province : Bangkok	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine Siriraj Hospital. Mahidol 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
