TCTR ID : TCTR20190115001

Overall Recruitment Status : Enrolling by invitation

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
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@mahidol.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 multidisciplinary 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 multidisciplinary 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 multidisciplinary 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
Completion Date (Last subject, Last visit) : 27 December 2018
Study Completion Date : 07 December 2020

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

<table>
<thead>
<tr>
<th>Central Contact</th>
<th>First Name : Arunotai</th>
<th>Middle Name :</th>
<th>Last Name : Siriussawakul</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree :</td>
<td>Phone : 02- 4197990 Ext. :</td>
<td>No Data</td>
<td>Email : <a href="mailto:arunotai.sir@mahidol.ac.th">arunotai.sir@mahidol.ac.th</a></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Central Contact Backup</th>
<th>First Name : Wasumadee</th>
<th>Middle Name :</th>
<th>Lastname : Ko-amornsup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree :</td>
<td>Phone : 086-7806632 Ext. :</td>
<td>No Data</td>
<td>Email : <a href="mailto:Chompoo.wkm@gmail.com">Chompoo.wkm@gmail.com</a></td>
</tr>
</tbody>
</table>

Section B Facility Information and Contact

1. Site Name : Arunotai Siriussawakul
   - City : No Data
   - State/Province : No Data
   - Recruitment Status : Enrolling by invitation

<table>
<thead>
<tr>
<th>Facility Contact</th>
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Section C : Contact for Public Queries (Responsible Person)

<table>
<thead>
<tr>
<th>First Name : Arunotai</th>
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<thead>
<tr>
<th>Postal Address : 2 WANG LANG Rd. BANGKOKNOI</th>
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<tbody>
<tr>
<td>Country : Thailand</td>
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<tr>
<td>Official Role : Study Principal Investigator</td>
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| Organization Affiliation : Faculty of Medicine Siriraj Hospital. Mahidol University |

Section D : Contact for Scientific Queries (Responsible Person)

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| 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