

TCTR ID : TCTR20230719001

Overall Recruitment Status : Completed (Has Results)

OTHER ID :

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

Tracking Information

First Submitted Date : 16 July 2023
First Posted Date : 19 July 2023
Last Update Posted Date : 12 July 2026

Title

Public Title : Optimizing Glycemic Control after Cardiac Surgery: A Trial of Protocol-Guided Nurse-Directed Versus Physician-Directed Insulin Adjustment: NUSULIN Trial
Acronym : No Data
Scientific Title : Efficacy of Insulin Infusion Protocol in Diabetic Patients after Cardiac surgery
Sponsor ID/ IRB ID/ EC ID : NU-IRB# P3-0046/2566
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20230719001>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : NU-IRB# P3-0046/2566
Date of Approval : 11 July 2023
Board Name : Institutional Review Board Naresuan University
Board Affiliation : Naresuan University, Thailand
Board Contact : Business Phone : 055965296 Ext. No Data
Business Email : nu-irb-board3@nu.ac.th
Business Address : 3rd Floor Sirindhorn Building, Naresuan University Hospital, Phitsanulok, 65000 Thailand

Sponsor

Source(s) of Monetary or Material Supports : Faculty of medicine, Naresuan University Hospital
Study Primary Sponsor : Faculty of medicine, Naresuan University Hospital
Responsible Party : Name/Official Title : Dr. Nisit Poolthananant
Organization : Faculty of medicine, Naresuan University Hospital
Phone : 055965666 Ext. No Data
Email : nisitpo@nu.ac.th
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : Hyperglycemia is one of the most earlier change after cardiac surgery. This effect increase the risk of postoperative complication and in-hospital mortality. The effect is more pronounced early after cardiac surgery especially during 48-72 hours after the surgery. Good glycemic control significantly affect outcomes after cardiac surgery.
Intensive glycemic control during early postoperative period after cardiac surgery usually require continuous insulin infusion with closed monitoring of blood glucose every 1-2 hours. In the standard treatment, insulin adjustment is conducted by the responsible surgeon. However, blood glucose level might be unstable and cannot remains in the desired level. There are reports of utilization of computerized protocol for glycemic control for medical personnel to follow which could improve the efficacy of glycemic control. We will investigate efficacy of computerized protocol vs standard treatment.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Efficacy of insulin infusion protocol in blood glucose control after cardiac surgery.
Keywords : Insulin, Infusion, Post cardiac surgery, Intensive care

Eligibility

Inclusion Criteria : 1. Patients undergoing elective open-cardiac surgery with cardiopulmonary bypass
and 2. Age 20-90 years
and 3. Established diagnosis of diabetes mellitus type2

Gender : Both

Age Limit : Minimum : 20 Years Maximum : 90 Years

Exclusion Criteria : Patients who underwent closed cardiac surgery
Patients undergoing emergency surgery.

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates	Study Start Date (First enrollment) : 01 July 2023	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 31 August 2025	Indicate Type : Actual
	Study Completion Date : 07 September 2025	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 2/Phase 3

Intervention Model : Parallel

Number of Arms : 2

Masking : Masked Masked Role : Allocation concealment, Subject, Investigator,

Allocation : Randomized

Control : No treatment / Standard of care

Study Endpoint Classification : Safety/Efficacy Study

Sample size

Planned sample size : 56

Actual sample size at study completion : 50

Intervention Arm 1

Intervention name : Paper-based insulin adjustment protocol

Intervention Type : Experimental

Intervention Classification : Other

Intervention Description : After finishing cardiac surgery, the patient will be transferred to the ICU. Blood glucose is checked via blood drawn from arterial line. The patient will received continuous insulin infusion. Insulin we used is regular insulin (Trade name: Actrapid). Insulin 100 units is mixed with normal saline 100 cc thus creates a concentration of 1:1. The ICU nurse is responsible for mixing, administering, and adjustment of insulin rate. 1. Blood sugar level is checked every 1-2 hours according to blood glucose level (protocol). 2. Insulin adjustment per protocol is performed by ICU nurse. 3. Serum electrolytes are checked every 2-6 hours according to blood glucose level (protocol). Our protocol (Naresuan Insulin Infusion Protocol) is a modification of Cleveland clinic's insulin infusion protocol which is reported by Olansky et al (Journal of Diabetes Science and Technology 2009). The protocol is a computerized model that ICU nurses can practice according to easily. We had conferences which cardiac surgeons, endocrinologists, pharmacists, and ICU nurses in order to create a suitable protocol for our units. We applied this protocol in a few patients during Jan 2023-April2023 which showed good results.

Intervention Arm 2

Intervention name : Insulin adjustment per surgeon's order

Intervention Type : Active Comparator

Intervention Classification : Other

Intervention Description : After finishing cardiac surgery, the patient will be transferred to the ICU. Blood glucose is checked via blood drawn from arterial line. The patient will received continuous insulin infusion. Insulin we used is regular insulin (Trade name: Actrapid). Insulin 100 units is mixed with normal saline 100 cc thus creates a concentration of 1:1. The ICU nurse is responsible for mixing, administering, of insulin. 1. Blood sugar level is checked every 1-2 hours 2. Insulin adjustment is perform by the ICU nurse according to surgeon's order 3. Serum electrolytes are checked according to insulin level. - If insulin rate is less than 5

units/hr, then electrolytes are checked every 6 hours - If insulin rate is 5-10 units/hr, then electrolytes are checked every 4 hours - If insulin rate is more than 10 units/hr, then electrolytes are checked every 2 hours
ICU nurse is responsible for notification of blood glucose level to the surgeon in case of; - Glucose level less than 100 mg/dL - Glucose level more than 200 mg/dL - Glucose level more than 400 mg/dL

Outcome

Primary Outcome

1. Outcome Name : Efficacy of insulin protocol

Metric / Method of measurement : Percentage of time blood glucose level remaining within target range

Time point : 0-72 hours after cardiac surgery

Secondary Outcome

1. Outcome Name : Safety and feasibility of insulin protocol

Metric / Method of measurement : 1. Time to target of glucose less than 150 mg/dL 2. Glycemic variability 3. Numbers of hypo/hyperkalemic events 4. Numbers of protocol violation by ICU nurse

Time point : 0-72 hours after cardiac surgery

Location

Section A : Central Contact

Central Contact	First Name : Nisit	Middle Name :	Last Name : Poolthananant
	Degree : MD.	Phone : 055965196 Ext. : No Data	Email : nisitpo@nu.ac.th
Central Contact Backup	First Name : Preaw	Middle Name :	Lastname : Suwannasrisuk
	Degree : MD.	Phone : 055965433 Ext. : No Data	Email : Praews@nu.ac.th

Section B Facility Information and Contact

1. Site Name : Naresuan university hospital

City : Mueang Phitsanulok District State/Province : Phitsanulok Postal Code : 65000

Country : Thailand Recruitment Status : Completed

Facility Contact	First Name : Nisit	Middle Name :	Last Name : Poolthananant
	Degree : MD.	Phone : 055965196 Ext. : No Data	Email : nisitpo@nu.ac.th

Facility Contact Backup	First Name : Preaw	Middle Name :	Last Name : Suwannasrisuk
	Degree : MD.	Phone : 055965433 Ext. : No Data	Email : Praews@nu.ac.th

Investigator Name	First Name : Nisit	Middle Name :	Last Name : Poolthananant
	Degree : MD.	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Nisit	Middle Name :	Last Name : Poolthananant
Degree : MD.	Phone : 055965196 Ext. : No Data	Email : nisitpo@nu.ac.th

Postal Address : Department of Surgery, Faculty of medicine, Naresuan University Hospital

State/Province : Phitsanulok Postal Code : 65000

Country : Thailand Official Role : Study Principal Investigator

Organization Affiliation : Faculty of medicine, Naresuan University Hospital

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Nisit	Middle Name :	Last Name : Poolthananant
Degree : MD.	Phone : 055965196 Ext. : No Data	Email : nisitpo@nu.ac.th

Postal Address : Department of Surgery, Faculty of medicine, Naresuan University Hospital

State/Province : Phitsanulok Postal Code : 65000

Country : Thailand Official Role : Study Principal Investigator

Organization Affiliation : Faculty of medicine, Naresuan University Hospital

Summary Results

Date of posting of results summaries : 31 May 2026

Date of first journal publication of results : Not yet published

Baseline Characteristics : 50 patients remained eligible. There were 25 patients in both groups. Demographic data were not statistically different between groups. Mean HbA1c levels were not different (IIP group: 6.82 and control group 7.13 mg/dL, p 0.403). Postoperatively, both groups received similar crystalloid fluids (p 0.16).

Participant Flow : All patients were preoperatively evaluated by the anesthesiologists. Intraoperative management was conducted according to standard protocols. After transfer to the ICU postoperatively, patients were randomly assigned to either the control group, which received physician-directed insulin infusion adjustment, or the insulin infusion protocol group (modified Cleveland Clinic insulin infusion protocol) (IIP) by using block randomisation method. Glycemic control in both groups was controlled by intravenous continuous insulin infusion. Regular insulin (Actrapid) 100 units in 100 mL of normal saline mixture. During the ICU postoperative period, blood tests were drawn from the arterial line every 1- 2 hours. In the control group, decisions regarding frequency of blood tests and insulin infusion rate are made at the physician's discretion. In the IIP group, the frequency of blood tests and insulin infusion rate were managed according to the modified Cleveland Clinic insulin infusion protocol (Supplemental Table 1). The target blood sugar in both groups was less than 150 mg/dL. Insulin infusion was discontinued if (1) 72 hours after ICU arrival or (2) oral feeding was started. After discontinuing insulin infusion, the endocrinologists were consulted to prepare for the transition of insulin infusion to subcutaneous insulin administration. Calculation of subcutaneous insulin is directed by endocrinologists on a case-by-case basis with no protocol at this time.

Adverse events : The incidence of hypoglycemia was higher in terms of the number of patient who developed hypoglycemia but not statistically significant (12% in IIP group vs 4% in control group, p 0.6). The magnitude of difference was smaller in terms of the number of blood tests (0.9% in IIP group vs 0.2 % in control group, p NA). Incidence of severe hypoglycemia (blood sugar less than 60 mg/dL) was not different as well. (Numbers of patients: 4% vs 0%, Blood tests: 0.19% vs 0%, p 1.0). Severe hypokalemia incidence was not significantly different. (4% in IIP group vs 0% in control group, p 1.0). Protocol deviations in the IIP group occurred in three patients (12%), but from blood readings, the incidence was only 0.56 %

Outcome Measures : Mean duration of insulin infusion was about 1.5 days in both groups. The IIP group has faster TTT than control group (2.95 hrs vs 6.11 hrs, respectively, p 0.002). TIR in IIP group was higher than control group (76.78% vs 58.5%, respectively, p 0.001). Average total insulin dose administered in both groups was not significantly different (p 0.61). Average insulin rate per hour in IIP group was higher than control group, though this was not statistically significant (1.49 units/hr in IIP group vs 1.24 units/hr in control group, p 0.34). The number of blood tests was not different (p 0.48).

Brief Summary of Results : There were 25 patients in both groups. Baseline characteristics showed no difference between groups. The IIP group had faster TTT (2.95 Hrs. vs 6.11 Hrs., p 0.002), better TIR (76.78 % vs 58.80 %, p 0.001), J-index in the IIP group is less than that of the control group (25.67 vs 33.76, p 0.002). There were some severe hypoglycemic events (4 % vs 0 %, p 1.00) and hypokalemic events (4 % vs 0 %, p 1.00).

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : Prohibited from university regulations. Need a consensus from colleagues.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data
