TCTR ID : TCTR20220412008

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

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

Tracking Information

First Submitted Date :	03 April 2022
First Posted Date :	12 April 2022
Last Update Posted Date :	12 April 2022

Title

Public Title :	Efficacy of Combine Dexamethasone and N-Acetylcysteine for prevent Post-embolization syndrome after Transarterial Chemoembolization in hepatocellular carcinoma (HCC) ,A double-blind, Randomized controlled trial
Acronym :	CD-NAC prevent PES
Scientific Title :	Efficacy of Combine Dexamethasone and N-Acetylcysteine for prevent Post-embolization syndrome after Transarterial Chemoembolization in hepatocellular carcinoma (HCC)
Sponsor ID/ IRB ID/ EC ID :	COA051/2564 (EC vajira)
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20220412008
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	COA024/2564
Date of Approval :	22 March 2021
Board Name :	INSTITUTIONAL REVIEW BOARD FACULTY OF MEDICINE VAJIRA HOSPITAL CERTIFICATE OF APPROVAL
Board Affiliation :	FACULTY OF MEDICINE VAJIRA HOSPITAL CERTIFICATE OF APPROVAL
Board Contact :	Business Phone : 022443843 Ext. No Data
	Business Email : ec.chayakrit@gmail.com
	Business Address : Institutional review board Vajira 681 samsen road Dusit district Bangkok 10300

Sponsor

Source(s) of Monetary or Material Supports :	Navamindradhiraj University Research Fund
Study Primary Sponsor :	Navamindradhiraj University Research Fund
Responsible Party :	Name/Official Title : Navamindradhiraj University Research Fund
	Organization : Faculty medicine, Navamindradhiraj University
	Phone : 0941496630 Ext. No Data
	Email : uraiwon@nmu.ac.th
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	This study patients with HCC BCLC A or B admitted for TACE were prospectively enrolled. All patients were randomized stratified by Child A or B to receive Dexamethasone plus NAC or placebo. The Dexa plus NAC group received intravenous dexamethasone 10 mg v q 12 hr plus NAC 24 h prior to TACE (150 mg/kg/h for 1 h followed by 12.5 mg/kg/h for 4 h, then continuous infusion 6.25 mg/h plus dexamethasone 8 mg v q 24 h for 48 h after the procedure). The placebo group received an infusion of 5% glucose solution until 48 h after procedure. Post embolization syndrome was defined by South west oncology group (SWOG) toxic code grading more than 2 that criteria using fever, nausea, vomiting and pain to calculated. And the secondary end point was Liver Decompensation after TACE and Length of hospital stay between two groups

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	To evaluate efficacy of Dexamethasone plus N-Acetylcysteine for prevention to develop Postembolization syndrome and Liver decompensation after TACE

Keywords : Hepatocellular carcinoma , post embolization syndrome , TACE , Transarterial Chemoembolization , Dexamethasone , N-Acetylcysteine , Liver Decompensation

Eligibility

Inclusion Criteria : Eligible individuals were inpatients aged between 18 to 80 years with diagnosed early or intermediate state HCC base on Barcelona Clinical Liver Cancer (BCLC) without main portal vein invasion and extrahepatic metastasis and fit (ECOG 0-1) for underwent TACE treatment. Criteria diagnosis of HCC was presence of histologically confirmed or radiologically diagnosed HCC (fulfilled criteria for lesions with typical imaging according to American Association for the study of Liver Disease (ASLD) Europian Association for the study of Liver (EASL) or Thai Association for the study of Liver (THASL).

Gender : Both

Age Limit : Minimum : 18 Years Maximum : 80 Years

Exclusion Criteria : The exclusion criteria were as follow
1.Decompensated Liver cirrhosis (child Pugh score more than 9)
2. congestive heart failure and/or respiratory failure
3. severe comorbid illness with expected life expectancy < 6 months (e.g. end stage renal disease , poor control DM or HbA1C > 8.5, Uncontrolled HT (SBP > 180 mmHg or DBP > 120 mmHg)
4. severe allergy or anaphylaxis/anaphylactoid to NAC or Drug interaction with nitroglycerine
5. pregnancy
6. History using of NSAID, Steroid, NAC with 21 days
7. Main portal vein invasion
8. refusal to participated in this study

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Completed

Key Trial Dates		
	Study Start Date (First enrollment) : 01 April 2021	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 26 January 2022	Indicate Type : Actual
	Study Completion Date : 28 February 2022	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 3

Intervention Model : Parallel

Number of Arms : 2

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

Allocation : Randomized

Control : Placebo

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 88

Actual sample size at study completion : 100

Intervantion Arm 1

Intervention name : Dexamethasone and N-Acetylcysteine

Intervention Type : Experimental

Intervention Classification : Drug

Intervention Description : The Dexa plus NAC group received intravenous dexamethasone 10 mg v q 12 hr plus NAC 24 h prior to TACE (150 mg/ kg/h for 1 h followed by 12.5 mg/kg/h for 4 h, then continuous infusion 6.25 mg/h plus dexamethasone 8 mg v q 24 h for 48 h after the procedure

Intervantion Arm 2

Intervention name : Placebo

Intervention Type : Active Comparator

Intervention Classification : Drug

Intervention Description : The placebo group received an infusion of 5% glucose solution until 48 h after procedure (Rate 60 ml/hr for 72 hr)

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Outcome

Primary Outcome

1. Outcome Name : development of post-embolization syndrome

Metric / Method of measurement : Post-embolization syndrome , Defined base on base on South west oncology group (SWOG) toxic coding more than 2 point

Time point : 6 weeks

Secondary Outcome

1. Outcome Name : Development of post-TACE liver decompensation and duration of admission between to group

Metric / Method of measurement : Development of post-TACE liver decompensation define as 1. TB rising more than 2 2.new onset Ascite 3.new HE 4.CPS score rising more than 2 and duration of admission between admit to discharg

Time point : 6 weeks

Location

Section A : Central Contact

Central Contact	First Name : nitipon	Middle Name :	Last Name : Simasingha
	Degree : Doctor of medicine	Phone : 0814009228 Ext. : No Data	Email : nitipon@nmu.ac.th
Central Contact Backup	First Name : Supasri	Middle Name :	Lastname : Srthasine
	Degree : Doctor of medicine	Phone : 0831879333 Ext. : No Data	Email : supatsri@nmu.ac.th

Section B Facility Information and Contact

1. Site Name : Gastroentrology unit, Mediciine division, faculty of medicine , Navaminthadhiraj university

	City : Bangkok	State/Province : Bangkok	Postal Code : 10300
	Country : Thailand	Recruitment Status : Completed	
Facility Contact	First Name : nitipon	Middle Name :	Last Name : simasingha
	Degree : Doctor of medicine	Phone : 0814009228 Ext. : No Data	Email : nitipon@nmu.ac.th
Facility Contact Backup	First Name : Supatsri	Middle Name :	Last Name : Sethasine
	Degree : Doctor of medicine	Phone : 0831879333 Ext. : No Data	Email : supatsri@nmu.ac.th
Investigator Name	First Name : nitipon	Middle Name :	Last Name : simasingha
	Degree : Doctor of medicine	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

	First Name : Nitipon	Middle Name :	Last Name : Simasingha
	Degree : Doctor of medicine	Phone : 0814009228 Ext. : No Data	Email : nitipon@nmu.ac.th
	Postal Address : 159/40 urbanorajvithi Bangplad		
	State/Province : Bangkok	Postal Code : 10700	
	Country : Thailand	Official Role : Study Principal Investigator	
	Organization Affiliation : Faculty of medicine , Navamintharadhiraj university		

Section D : Contact for Scientific Queries (Responsible Person)

	First Name : Nitipon	Middle Name :	Last Name : Simasingha
	Degree : Doctor of medicine	Phone : 0814009228 Ext. : No Data	Email : nitipon@nmu.ac.th
	Postal Address : GI Unit 681 vajira hospitol dusit		
	State/Province : Bangkok	Postal Code : 10300	
	Country : Thailand	Official Role : Study Principal Investigator	
	Organization Affiliation : Faculty of medicine , Navamintharadhiraj university		

Summary Results

Date of posting of results summaries : 09 March 2022

Date of first journal publication of results : Not yet published

Baseline Characteristics : The mean aged of participant was 60.8 years with male predominate in both 2 groups Type 2 DM in both group no statically significant 34 in DEXA & NAC and Placebo group . Chronic hepatitis B and alcohol is second most common in both 2 groups and mostly patient were in Child Pugh A . In both 2 group mainly were diagnosis HCC BCLC B and few patient whom underwent TACE for bridging therapy before definitive treatment. Pertaining to tumor characteristic AFP were not statically significant in both 2 group Median tumor sized are 5.5 in DEXA & NAC group and 7.95 and one of third patient was first TACE session No statically significant in both 2 group in the part of embolizing agent

Participant Flow :	At least 24 h before the prescheduled TACE all patients were admitted to the hospital for preprocedural evaluation and preparation. Patients who were agreed to participate were randomly assigned in a 1:1 ratio to NAC and dexamethasone group or placebo group. The randomization sequence was generated by computer in a block of four . All patients were blinded to treatment assignment. In patients randomized to NAC and dexamethasone group, infusion of 5%dextrose with NAC was begun with an initial loading dose of 150 mg/kg/hr of NAC over 2 hours followed by 12.5 mg/kg/hr for 4 hours plus dexamethasone 10 mg intravenously q 12 hours then continuous infusion of 6.25 mg/kg/hr (rate IV total 60 ml/Hr) of NAC and 4 mg intravenously q 12 hr for the remaining 48 hours after TACE. In placebo group 5% glucose solution was given until 48 hour (rate IV 60 ml/hours) after TACE
Adverse events :	There were two patients in the DEXA and NAC group developed mild allergic skin reaction during receiving the study medication. However all the reactions spontaneously resolved after drug discontinuation and all patients were able to complete the study medication after a readministration of NAC at a lower infusion rate. No serious adverse events were reported in both groups. There were one patients randomized to the placebo group died within 90 days after the procedure due to severe sepsis with liver decompensation Despite people who were developed fever after TACE no patients had an acute bacterial infection during hospital stay. In the concerning of Hyperglycemia after receive dexamethasone and placebo there were not significant hyperglycemia (Grade 3 CTCAE as BS between 250 to 500) in both group and not significant underlying T2DM in both group (17 (34%) VS 16 (32%) P-value 0.832 respectively DEXA and NAC and Placebo) Aspartate Aminotransferase (AST) Alanine Aminotransferase (ALT) Alkaline phosphate (ALP) were not significant grading according CTCAE in both group However serum total bilirubin were significant higher grade 3 and 4 transient hyperbilirubinemia in placebo group 58 % vs 18 % in DEXA and NAC
Outcome Measures :	According to predefine criteria, South west oncology group (SWOG) toxic code , Siramonpiwat and Ogasawara. Post-embolization syndrome was document in 43/100 patients. As shown in Figure 2 the development of Postembolization syndrome after TACE was significantly lower in patients randomized to DEXA+NAC group than in the placebo group (6% VS 80 % defined by SWOG criteria multivariate analysis DEXA+NAC is protective factor against PES with an OR of 0.04
Brief Summary of Results :	100 patients were enrolled 50 patients were randomly assigned to dexamethasone plus NAC and placebo were significantly lower developed PES in dexamethasone and NAC than placebo group (6 % VS 80 % P 0.001) and multivariate analysis DEXA and NAC is protective factor against PES with an OR of 0.04 (P 0.001) Post-TACE liver decompensation was documented in 7 from 50 (14 %) in control group

Deidentified Individual Participant-level Data Sharing

Plan to share IPD :	No
Reason :	personal data

Publication from this study

MEDLINE Identifier :	No Data
URL link to full text publication :	No Data

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