TCTR ID : TCTR20210812003

OTHER ID :

Overall Recruitment Status : Active, not recruiting

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

Tracking Information

First Submitted Date :	11 August 2021
First Posted Date :	12 August 2021
Last Update Posted Date :	26 June 2024

Title

Public Title :	HYPOfractionated Whole Pelvic Concurrent Chemoradiotherapy in Cervical (Cx) Cancer with Indirect Excess Dose Volume Ratio (iRex) - Optimized Image Guided Adaptive Brachytherapy (HYPOCx-iRex Trial): A Phase II Non-inferiority Randomized Controlled Trial
Acronym :	HYPOCx-iRex Trial
Scientific Title :	HYPOfractionated Whole Pelvic Concurrent Chemoradiotherapy in Cervical (Cx) Cancer with Indirect Excess Dose Volume Ratio (iRex) - Optimized Image Guided Adaptive Brachytherapy (HYPOCx-iRex Trial): A Phase II Non-inferiority Randomized Controlled Trial
Sponsor ID/ IRB ID/ EC ID :	149/2564(IRB3)
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20210812003
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	COA no. Si436/2021
Date of Approval :	21 June 2021
Board Name :	Siriraj Institutional Review Board (SIRB)
Board Affiliation :	Human Research Protection Unit. Faculty of Medicine Siriraj Hospital, Mahidol University
Board Contact :	Business Phone : 024192667 Ext. 72
	Business Email : siethics@mahidol.ac.th
	Business Address : 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 :	Faculty of Medicine, Siriraj Hospital, Mahidol University
Study Primary Sponsor :	Faculty of Medicine, Siriraj Hospital, Mahidol University
Responsible Party :	Name/Official Title : Division of Radiation Oncology, Department of Radiology
	Organization : Faculty of Medicine, Siriraj Hospital, Mahidol University
	Phone : 024198674 Ext. No Data
	Email : pittaya.dan@mahidol.ac.th
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	HYPOCx-iRex trial is conducted to investigate the feasibility and safety of 20-fraction whole pelvic external radiotherapy (EBRT) comparing to the conventional 25-fraction EBRT -- standard EBRT for cervical cancer definitive chemoradiation. Moreover, the novel spatial constraint, called indirect ratio of excess dose volume (iRex), is also explored in the brachytherapy sessions to facilitate dose-expansion, in addition to small volume DVH parameters, especially D2cc. Objectives: Primary Objective: Investigate the feasibility and safety of 44Gy/20fraction (2.2Gy/F) comparing to 45Gy/25F (1.8Gy/F) EBRT in cervical cancer definitive chemoradiation. Secondary Objectives: Investigate the efficacy of iRex and D2cc parameters comparing to D2cc alone in cervical cancer IGABT. Population: 40 Female with more than 18-year-old, Early and locally advanced cervical cancer with intact cervix Phase: 2 single-institute

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Early and locally advanced cervical cancer with intact cervix Hypofractionated whole pelvic concurrent chemoradiotherapy Indirect Excess Dose Volume Ratio (iRex) - optimized Image Guided Adaptive Brachytherapy (iRex-IGABT)
Keywords :	cervical cancer, uterine Hypofractionation, Radiotherapy Dose Brachytherapy Indirect Excess Dose Volume Ratio (iRex)

Eligibility

Inclusion Criteria :	1. Cancer of the uterine cervix considered suitable for curative treatment with definitive radio-(chemo)therapy including imaged-guided BT 2. Positive biopsy showing squamous-cell carcinoma, adenocarcinoma, or adeno-squamous cell carcinoma of the uterine cervix 3. Staging according to FIGO 2018 and TNM guidelines 4. MRI of the pelvis at diagnosis is performed 5. MRI, CT, or PET-CT of the retroperitoneal space and abdomen at diagnosis is performed 6. MRI with the applicator in place at the time of (first) BT will be performed 7. GFR >/= 50 mL/min 8. Patient informed consent
Gender :	Female
Age Limit :	Minimum : 18 Years Maximum : N/A (No limit)
Exclusion Criteria :	1. Other primary malignancies except carcinoma in situ of the cervix and basal cell carcinoma of the skin 2. Small cell neuroendocrine cancer, melanoma and other rare cancers in the cervix 3. Metastatic disease at, above, and beyond the common iliac node or 3 any pathologic nodes or more. 4. Previous pelvic or abdominal radiotherapy 5. Previous total or partial hysterectomy 6. Combination of preoperative radiotherapy with surgery 7. Patients receiving BT only 8. Patients receiving EBRT only 9. Patients receiving neo-adjuvant chemotherapy or other forms of antineoplastic treatment apart from weekly concomitant cisplatin (40 mg/m2). 10. Contra-indications to MRI 11. Contra-indications to BT
Accept Healthy Volunteers :	No

Status

Overall Recruitment Status :	Active, not recruiting	
Key Trial Dates	Study Start Date (First enrollment) : 02 July 2021	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 02 June 2028	Indicate Type : Anticipated
	Study Completion Date : 02 June 2028	Indicate Type : Anticipated

Design

Study Type :	Interventional
Primary Purpose :	Treatment
Study Phase :	Phase 2/Phase 3
Intervention Model :	Parallel
Number of Arms :	4
Masking :	Masked Masked Role : Allocation concealment, Outcome Assessor, Statistician
Allocation :	Randomized
Control :	Active
Study Endpoint Classification :	Safety/Efficacy Study
Sample size	
	Planned sample size : 40
Intervantion Arm 1	
	Intervention name : HYPO-iRex
	Intervention Type : Experimental
	Intervention Classification : Radiation

Intervention Description : Hypofractionated IMRT/VMAT 44Gy/20F followed by iRex-oriented IGABT

Intervantion Arm 2

Intervention name : HYPO-D2cc
Intervention Type : Experimental
Intervention Classification : Radiation
Intervention Description : Hypofractionated IMRT/VMAT 44Gy/20F followed by D2cc-oriented IGABT

Intervantion Arm 3

Intervention name : CVRT-iRex
Intervention Type : Experimental
Intervention Classification : Radiation
Intervention Description : Conventional IMRT/VMAT 45Gy/25F followed by iRex-oriented IGABT

Intervantion Arm 4

Intervention name : CVRT-D2cc
Intervention Type : Active Comparator
Intervention Classification : Radiation
Intervention Description : Conventional IMRT/VMAT 45Gy/25F followed by D2cc-oriented IGABT

Outcome

Primary Outcome

1. Outcome Name : Acute toxicity incidence
Metric / Method of measurement : CTCAE
Time point : during treatment; and at 1- and 3-month follow up after treatment
2. Outcome Name : Chronic toxicity incidence
Metric / Method of measurement : CTCAE
Time point : at 6-, 12-month, and 3-, 5-year follow up after treatment

Secondary Outcome

1. Outcome Name : Tumor response rate
Metric / Method of measurement : RECIST 1.1
Time point : post-EBRT period; and at 3-, 6-, and 12-month follow up after treatment
2. Outcome Name : Quality of life
Metric / Method of measurement : EORTC QLQ-C30, CX24, EN24
Time point : during treatment; and at 1-, 3-, 6-, 12-month, and 3-, 5-year follow up after treatment
3. Outcome Name : Local and nodal recurrence free, metastatic free, disease-specific, and overall survival rate
Metric / Method of measurement : Clinical exam and abdominopelvic CT/MRI as clinically indicated
Time point : at 3-, 5-year follow up after treatment
4. Outcome Name : Dosimetric data of EBRT and IGABT
Metric / Method of measurement : Dose reports in treatment planning system
Time point : after radiation delivery
5. Outcome Name : Number of fractions with successful iRex optimization
Metric / Method of measurement : Dose reports in treatment planning system
Time point : after radiation delivery

Location

Section A : Central Contact

Central Contact	First Name : Pittaya	Middle Name :	Last Name : Dankulchai
	Degree : MD	Phone : 0892029201 Ext. : No Data	Email : pittaya.dan@mahidol.ac.th
Central Contact Backup	First Name : Tissana	Middle Name :	Lastname : Prasartseree
	Degree : MD	Phone : 0625246101 Ext. : No Data	Email : tissana.p@gmail.com

Section B Facility Information and Contact

1. Site Name : Department of Radiation Oncology , Division of Radiology, Faculty of Medicine
City : Bangkok noi | State/Province : Bangkok | Postal Code : 10700

	Country : Thailand	Recruitment Status : Pending (Not yet recruiting)	
Facility Contact	First Name : Pittaya	Middle Name :	Last Name : Dankulchai
	Degree : MD	Phone : 0892029201 Ext. : No Data	Email : pittaya.dan@mahidol.ac.th
Facility Contact Backup	First Name : Tissana	Middle Name :	Last Name : Prasartseree
	Degree : MD	Phone : 0625246101 Ext. : No Data	Email : tissana.p@gmail.com
Investigator Name	First Name : Tissana	Middle Name :	Last Name : Prasartseree
	Degree : MD	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Tissana	Middle Name :	Last Name : Prasartseree
Degree : MD	Phone : 0625246101 Ext. : No Data	Email : tissana.p@gmail.com
Postal Address : 72nd Anniversary building, Siriraj hospital, 2, Wanglang Rd, Siriraj, Bangkok noi		
State/Province : Bangkok	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Division of Radiation Oncology, Department of Radiology, Faculty of Medicine, Siriraj Hospital, Mahidol University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Tissana	Middle Name :	Last Name : Prasartseree
Degree : MD	Phone : 0625246101 Ext. : No Data	Email : tissana.p@gmail.com
Postal Address : 72nd Anniversary building, Siriraj hospital, 2, Wanglang Rd, Siriraj, Bangkok noi		
State/Province : Bangkok	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Division of Radiation Oncology, Department of Radiology, Faculty of Medicine, Siriraj Hospital, Mahidol University		

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : The informed consents did not cover the IPD sharing.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data