

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

evaluation the effectiveness of neoadjuvant chemoradiation in patient with borderline and unresectable pancreatic cancer

Protocol summary

Study aim

Evaluation of the effect of neoadjuvant chemotherapy and chemoradiotherapy in patients with Borderline pancreatic cancer and non-metastatic unresectable pancreatic cancer in achieving negative surgical margin

Design

clinical trial Phase 2 on 18 patients without control group

Settings and conduct

Patients referred to the Firoozgar Hospital Radiotherapy or Surgery Clinic, who are classified according to the NCCN Criteria, to borderline and non-metastatic unresectable pancreatic cancer. Liver and kidney functional test and Alb, CEA, CA19-9, CBC DIFF will be taken. They are treated with mFOLFIRINOX regimes and then after two to four weeks, patients undergoing chemoradiotherapy with mXELOX. Thereafter, after 4-6 weeks they undergo a CT scan and are evaluated by a team of surgeons and radiation oncologists to assess resectability. If patients do not have a metastasis and the tumor is resectable, surgery would be performed and surgical margins would be evaluated.

Participants/Inclusion and exclusion criteria

Patients over the age of 18 to 75 years who have not previously received chemotherapy or radiotherapy in the upper abdomen, as well as the functional status of group 0 or one according to the ECOG Criteria. Patients should have acceptable results from the initial tests that show organ function, as follows: .AST, ALT <2ULN .BILI <20 .INR NL. Cr NL WBC> 3000 .Hb> 9 .Platelet> 100,000.

Intervention groups

Radiotherapy is performed in 3D Conformal. And with a daily dose of 1.8 Gy to a total dose of 45 Gy in 25 fraction five days a week to the GTV area combined with mXELOX chemotherapy regimes .

Main outcome variables

negative surgical margin in patients with pancreatic cancer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170306032913N5**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Alireza Nikoofar

Name of organization / entity

Firoozgar Clinical Research Development Center (FCRDC)

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation the effectiveness of neoadjuvant chemoradiation in patient with borderline and unresectable pancreatic cancer

Public title

the effectiveness of neoadjuvant chemoradiation in patient with pancreatic cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over the age of 18 to 75 years who have not previously received chemotherapy or radiotherapy in the upper abdomen, , acceptable liver, kidney, and lung function, and acceptable CBC diff the functional status of group 0 or one according to the ECOG definition. Patient with borderline and unresectable nonmetastatic pancreatic cancer

Exclusion criteria:

Serious concomitant systemic disorder Women with a positive pregnancy test or lactating Previously radiotherapy of upper abdomen Have endocrine pancreatic tumors or ampullary cancer Pathology other than pancreatic adenocarcinoma

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

initial chemotherapy with mfolfirinox regimes then chemoradiation with capox regimes and then if not metastatic referred to surgery and the end evaluation of negative margins of surgery

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran international committee for ethics biomedical

research

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behafarin st.karim khan st, valiasr square, tehran,

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Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.IUMS.FMD.REC.1399.133

Health conditions studied**1****Description of health condition studied**

Pancreatic cancer

ICD-10 code

C25

ICD-10 code description

Malignant neoplasm of pancreas

Primary outcomes**1****Description**

the rate of negative surgical margin

Timepoint

the end of neoadjuvant therapy

Method of measurement

pathological evaluation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: MFOLFIRINOX chemotherapy regimens (Oxalipaltin 85mg / m2 — leucovorin calcium 400mg / m2— Irinotecan 150 mg / m2 --- Fluorouracil 2400mg / m2 continuous infusion over 46h are treated then under CT Simulation after two to four weeks. Radiotherapy is given to patients in supine position without oral and intravenous contrast with a thickness of three millimetres, GTV is contouring with radiation oncologist according to the RTOG protocol, and radiotherapy is performed as 3D Conformal radiotherapy. The GTV includes a tumor seen on a CT scan, and the CTV includes tumor with a margin of 1.5 cm. Patients' lymph nodes are not treated electives. Patients are treated by a physics and radiation oncologist team, and patients are treated for 5 weeks 5 days a week at a daily dose of 1.8 Gy to a total dose of 45 GHz. They are visited twice a week by a doctor and are treated with mXELOX

regimes during radiotherapy according to the following protocol; cap capecitabin 625mg/m² BID and oxaliplatin injection drug at a dosage of 65 mg / m² from the first day of radiotherapy weekly for two weeks followed by a week of rest and then weekly for two weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firozgar hospital

Full name of responsible person

Nikoofar Alireza

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

majid kaheh

Position

resident of radiation oncology

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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resident of radiooncology

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available