Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 combind 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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Email address

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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
Street address
behafarin st.karim khan st,valiasr square,tehran,
City
tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
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 continous infusion over 46h are treated then under CT Simmulation 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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Firoozgar Hospital, Beh Afarin St,Karim Khan St, Valiasr Square,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nikoofar alireza

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

resident of radiooncology

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

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majid kaheh
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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