Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Pharmacokinetic evaluation of Paclynap formulation in comparison with Abraxan in pancreatic cancer patients

Protocol summary

Summary

Paclitaxel is widespreadly used in chemotherapy diets due to its antitumor activity, which causes severe and even lethal toxicity and also severe allergic reactions. Abraxan is an albumin-bound formulation derived from Paclitaxel which lacks paclitaxel-related toxicities. Recently, a formulation similar to Abraxan, nemed Paclinab, have been produced which in vitro studies indicate its acceptable function. Therefore, this study is aimed to evaluate Paclinab efficiency and its comparison with Abraxan in pancreatic cancer patients. This study will perform in two groups, on twenty pancreatic cancer patients with a randomized crossover diet containing paclitaxel for comparison of Paclinab and Abraxan formulations. In the first cycle, one group will receive a dosage of Paclinab and another one will receive a dosage of Abraxan (125 mg/m2 of body surface area during 30 min infusion), under medical care. In next cycle (3-week cycles) the group which received Abraxan, will receive Paclinab and the other group will receive the drug with the same dosage, vice versa. assessment of blood samples will be done for comparison of pharmacokinetic parameters of both formulations at different times, before the infusion initiation, 15 min after the infusion initiation, 2-5 min before the infusion termination, and also 30 min, 1 h, 1.5 h, 2 h, 4 h, 6 h, 8 h, 12 h, 24 h and 48 h after infusion termination. Measurement of Paclitaxel is performed in all samples using a high fluid pressure chromatography analysis method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041118745N4**
Registration date: **2016-06-10, 1395/03/21**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-06-10, 1395/03/21

Registrant information

Name
Ali Mohammad Alizadeh
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6119 2501
Email address
aalizadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Nano Daru Pajuhan Pardis Co

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic evaluation of Paclynap formulation in comparison with Abraxan in pancreatic cancer patients

Public title

Evaluation of blood levels of Paclynap produced drug in Iran in comparison with Abraxan in pancreatic cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: with written consent; patients with Local Advanced Pancreatic Cancer. exclusion criteria: patients with hepatic and renal disorders; patients with acute and chronic heart disease; patients with pulmonary and cerebral metastasis; patient with decreased albumin levels of two times of normal; patients with enhanced blood bilirubin of 3 times over.

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University Vice Chancellor for Research and Technology, Quds Street intersection with Keshavarz Bulvar, Tehran

City

Tehran

Postal code

Approval date

2016-04-06, 1395/01/18

Ethics committee reference number

IR.TUMS.REC.1395.2323

Health conditions studied

1

Description of health condition studied

Pancreas cancer

ICD-10 code

C25

ICD-10 code description

Malignant neoplasm of pancreas

Primary outcomes

1

Description

Paclytaxel serum level

Timepoint

30 min, one, two, four, six, eight, twelve, twenty four, forty eight hours after injection

Method of measurement

High fluid pressure chromatography

Secondary outcomes

1

Description

decrease of tumor

Timepoint

Two months after injection

Method of measurement

Imaging using MRI

Intervention groups

1

Description

The randomized crossover study will be performed on two groups. The first group which will initially receive abraxan: This group will initially receive abraxan (125 mg / m2 of body surface area at the first cycle at days 1, 8 and 15). Then in the next cycle, after one week relaxation, the patients will receive paclinab (125 mg / m2 of body surface area at days 28, 35 and 42).

Category

Treatment - Drugs

2

Description

The second group which will initially receive paclynap: This group will initially receive paclynap (125 mg / m2 of body surface area at the first cycle at days 1, 8 and 15). Then in the next cycle after one week relaxation, the patients will receive abraxan (125 mg / m2 of body surface area at days 28, 35 and 42).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Cancer Institute

Full name of responsible person
Dr. Ali Mohammad Alizadeh
Street address
Cancer Research Center, Cancer Institute, Keshavarz Blvd.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nano Daru Pajuhan Pardis Co
Full name of responsible person
Navid Goodarzi
Street address
unit 2, No. 33, Bagher Street East, Chamran Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nano Daru Pajuhan Pardis Co
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammad Alizadeh
Position
PhD
Other areas of specialty/work
Street address
Cancer Research Center, Cancer Institute, Keshavarz Blvd.
City
Tehran
Postal code
Phone
+98 21 6119 2798
Fax
Email
aalizadeh@sina.tums.ac.ir
Web page address
www.pccrg.org

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammad Alizadeh
Position
PhD
Other areas of specialty/work
Street address
Cancer Research Center, Cancer Institute, Keshavarz Blvd.
City
Tehran
Postal code
Phone
+98 21 6119 2798
Fax
Email
aalizadeh@sina.tums.ac.ir
Web page address
pccrg@org

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammad Alizadeh
Position
PhD
Other areas of specialty/work
Street address
Cancer Research Center, Cancer Institute, Keshavarz Blvd.
City
Tehran
Postal code
Phone
+98 21 6119 2798
Fax
Email
aalizadeh@sina.tums.ac.ir
Web page address
pccrg@org

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty