

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

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

Protocol summary

Summary

Paclitaxel is widely used in chemotherapy regimens 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, named 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 design 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

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Email address

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Recruitment status

Recruitment complete

Funding source

Nano Daru Pajuhani 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 Paclynab formulation in comparison with Abraxan in pancreatic cancer patients

Public title

Evaluation of blood levels of Paclynab 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

Paclitaxel 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 paclitaxel (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 paclitaxel: This group will initially receive paclitaxel (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

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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

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

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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