Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the safety and efficacy of sodium pentaborate pentahydrate in patients with advanced renal cell carcinoma: An open-label single-arm phase 1b/2 trial

Protocol summary

Study aim
Evaluation of the safety and effectiveness of sodium pentaborate pentahydrate in patients with advanced renal cell carcinoma

Design
An open-label phase 1/2 clinical trial study will be conducted on approximately 30 participants with advanced renal cell carcinoma.

Settings and conduct
This study will be conducted in hospitals affiliated with Tabriz University of Medical Sciences. Patients are grouped in groups of 3 to 6 using a “3 plus 3” design, and dosing starts at a dose level of 500 mg NaB. The dose-limiting toxicity (DLT) evaluation period will be 21 days. All available safety and pharmacodynamic information is considered in the decision to increase or decrease the dose of the next group or to expand the current group.

Participants/Inclusion and exclusion criteria
Patients with (RCC) aged 18 years or older who have histological confirmation with clear cell histology and have advanced or metastatic disease will be included.

Intervention groups
The intervention group will receive an oral capsule of sodium pentaborate pentahydrate once a day for evaluation in 21-day treatment periods at three treatment doses of 500 mg, 1000 mg and 1500 mg.

Main outcome variables
Determination of maximum tolerated dose and/or recommended dose; Estimating the objective response rate (ORR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220614055167N4**
Registration date: **2023-03-26, 1402/01/06**
Registration timing: **prospective**

Last update: **2023-03-26, 1402/01/06**
Update count: **0**

Registration date
2023-03-26, 1402/01/06

Registrant information

Name
Saeid Safiri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2025-05-22, 1404/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the safety and efficacy of sodium pentaborate pentahydrate in patients with advanced renal cell carcinoma: An open-label single-arm phase

1b/2 trial

Public title

Evaluation of the safety and efficacy of sodium pentaborate pentahydrate in patients with advanced renal cell carcinoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years or older Histological confirmation of RCC with clear cell histology, including participants who may also have sarcomatoid features Advanced (not amenable to curative surgery or radiation) or metastatic disease (American Joint Committee on Cancer [AJCC] stage IV) Karnofsky status degree (KPS) 70% Participants with optimal, moderate and poor risk categories will be eligible for the study. Participants had to be stratified according to the International Metastatic RCC Database Consortium (IMDC) criteria according to favorable versus moderate versus poor risk status Sufficient blood and organ function, based on meeting all the following laboratory criteria in the 14 days before the first dose of study treatment No prior systemic therapy for RCC with the following exception: one prior adjuvant or neoadjuvant therapy for fully resectable RCC if such therapy did not contain an agent targeting vascular endothelial growth factor (VEGF) or VEGF receptors and if at least 6 months Relapse occurred after the last dose of adjuvant or neoadjuvant treatment Measurable disease according to RECIST v1.1 according to the researcher Patients who are willing and able to provide informed consent/written consent for the trial Sexually active fertile patients and their partners must agree to use highly effective methods of contraception that alone or in combination with continuous and correct use during the study and for 5 months after the last dose of study treatment results in Failure to be less than 1% per year. An additional method of contraception, such as a barrier method (such as a condom), is recommended Negative pregnancy test (urine or serum beta-human chorionic gonadotropin [β-hCG]) in screening women of reproductive potential who are sexually active.

Exclusion criteria:

Women who are pregnant, lactating or planning to become pregnant within 3 months after the last dose of the study drug and men who plan to have a child while enrolled in this study or within 5 months after the last dose of the study drug Any active central nervous system (CNS) metastasis. Participants with treated and stable CNS metastases for at least one month were eligible Any tumor that invades the superior vena cava (SVC), other major blood vessels, or the gastrointestinal tract. Any evidence of intratracheal or intrabronchial tumor Prior systemic therapy with VEGF, MET, AXL, KIT, or RET targeted therapy (including, but not limited to, sunitinib, pazopanib, axitinib, tivozanib, sorafenib, lenvatinib, bevacizumab, and cabozantinib) Previous treatment with anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody, or any other antibody or drug that specifically co-stimulates the cells Targets T or checkpoint routes History of autoimmune disease requiring systemic therapy (eg, using disease-modifying agents, corticosteroids, or immunosuppressive drugs) within the past 2 years Diagnosis of immunodeficiency or receiving treatment with systemic steroid or any other form of immunosuppressive therapy within two weeks before the first dose of experimental treatment. Administration of a live attenuated vaccine within 30 days before the first dose of study treatment The patient has an uncontrolled or significant intermediate disease Hematuria, hematemesis, or hemoptysis of more than 0.5 teaspoons (2.5 mL) of clinically significant red blood, or other history of significant bleeding (eg, pulmonary hemorrhage) in the 12 weeks prior to the first dose Cavity lung lesions or known manifestations of endobronchial disease Injury to a major blood vessel including, but not limited to, the inferior vena cava, pulmonary artery, or aorta Known psychiatric or substance abuse disorders that interfere with compliance with trial requirements. History or current evidence of any condition, treatment, or laboratory abnormality that may confound the results of the trial, interfere with the patient's participation throughout the trial, or in the opinion of the treating investigator would not be in the patient's best interest to participate The participant is currently participating in a study of another investigational agent and has received study treatment or used an investigational device within 4 weeks prior to the first dose of treatment Allergy or previous hypersensitivity to the components of the studied therapeutic formulation has been identified. Patients with a history of infusion-related reactions to prior therapy may be eligible with sponsor approval if the reaction is considered mild and manageable with appropriate supportive care (eg, use of prodrugs per standard of care) Subjects with evidence of active malignancy other than RCC (except for definitively curable early-stage cancer such as resected skin cancers and/or completely resected prostate cancer)

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Azadi St., Golgasht Ave., Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2023-03-06, 1401/12/15
Ethics committee reference number
IR.TBZMED.REC.1401.1092

Health conditions studied

1

Description of health condition studied
Advanced renal cell carcinoma
ICD-10 code
C64
ICD-10 code description
Malignant neoplasm of kidney, except renal pelvis

Primary outcomes

1

Description
Determination of maximum tolerated dose (MTD) and/or recommended dose
Timepoint
Days 0, 1 and 21
Method of measurement
Response Evaluation Criteria in Solid Tumors version 1.1

2

Description
Determination of objective response rate
Timepoint
Days 0, 1 and 21
Method of measurement
Response Evaluation Criteria in Solid Tumors version 1.1

Secondary outcomes

1

Description
Duration of response
Timepoint
Days 0, 1 and 21
Method of measurement
Response Evaluation Criteria in Solid Tumors version 1.1

2

Description
Progression free survival
Timepoint
Days 0, 1 and 21
Method of measurement
Response Evaluation Criteria in Solid Tumors version 1.1

3

Description
Disease control rate
Timepoint
Days 0, 1 and 21
Method of measurement
Response Evaluation Criteria in Solid Tumors version 1.1

4

Description
Overall survival
Timepoint
Days 0, 1 and 21
Method of measurement
Response Evaluation Criteria in Solid Tumors version 1.1

5

Description
Adverse events
Timepoint
Days 0, 1 and 21
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Capsules containing sodium pentaborate pentahydrate 500, 1000 and 1500 mg with the chemical formula B4H10Na2O12 will be used. Capsules are taken once a day. The treatment period will last for 21 days. Medicines will be prepared by Tabriz Faculty of Pharmacy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences
Full name of responsible person

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Sponsors / Funding sources

1

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Web page address
https://www.tbzmed.ac.ir/
Grant name
Research Deputy of Tabriz University of Medical Sciences
Grant code / Reference number
70926
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Saeid Safiri
Position
Assistant Professor
Latest degree
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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
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All of the information will be available to all after publishing without the personal information of participants.
When the data will become available and for how long
After publishing the papers
To whom data/document is available
All researchers that are confirmed by the principal investigator
Under which criteria data/document could be used
All of the data will be available except the personal information of the participants
From where data/document is obtainable
Applicants can initially communicate with the principal investigator's email that is available in this protocol, and if there is no response within a week, a reminder email will be sent again. If they still do not receive an answer, they can call the relevant contact number or send a letter to the listed postal address.
What processes are involved for a request to access data/document
It is evaluated by the team and the principal investigator will inform those who requested
Comments