

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Evaluation of minocycline effect on reducing the volume of ascites and the tumor markers of VEGF and IL-6 before and after the usage of the drug in patients with resistant malignant ascites

Protocol summary

Study aim

To determine the efficacy of Minocycline in the treatment of malignant resistant ascites and to identify its mechanism and to specify the required dose by the Escalating method.

Design

This project will be conducted as a clinical study within 8 weeks. The number of patients according to the statistical calculations and the rarity of the conditions have been identified as 4, with a possible 25% drop, 6 patients will enter the study. At first, ascitic fluid volume is determined by ultrasound then samples are taken from the ascites fluid and blood. The collected blood and ascites samples on days 0, 15, 30, 45 and 60, a total of ten samples per patient, will be measured for tumor markers, VEGF and IL-6, before and after treatment with minocycline using ELISA kit and will be analyzed and compared at different times and doses. Meanwhile, the extent of the ascites fluid, which is determined by ultrasound, will be evaluated at different times.

Settings and conduct

Patients with malignant ascites referred to the oncology clinic of Taleghani Hospital of Shahid Beheshti University of Medical Sciences (Evin, Tehran), who are in the final stages of the disease and did not respond to other commonly used medications.

Participants/Inclusion and exclusion criteria

Patients with Advanced Cancer and Malignant resistant Ascites

Intervention groups

Evaluating the approximate ascites volume and treatment with escalating doses of minocycline and comparing each individual with him at different times and doses within two months

Main outcome variables

The volume of ascitic fluid, The tumor markers of VEGF (Vascular Endothelial Growth Factor) and IL-6

(Interleukin-6),

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140113016200N2**

Registration date: **2019-03-04, 1397/12/13**

Registration timing: **prospective**

Last update: **2019-03-04, 1397/12/13**

Update count: **0**

Registration date

2019-03-04, 1397/12/13

Registrant information

Name

Khojasteh Joharchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of minocycline effect on reducing the volume of ascites and the tumor markers of VEGF and IL-6 before and after the usage of the drug in patients with resistant malignant ascites

Public title

The Evaluation of minocycline effect in patients with resistant malignant ascites

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Have metastatic progressive cancer and resistant malignant ascites with no answer to the routine treatments. older than 18 years. Complete written informed consent form in accordance with Ministry of Health guidelines included in this study. Have healthy liver and kidney function. Have estimated lifetime of at least 12 weeks. Should have a measurable disease according to the criteria for evaluation of response to solid tumors (RECIST). At least 3 weeks after the past chemotherapy for improvement of reversible side effects (and at least 6 weeks for chemotherapy drugs that have toxic effects on the stem cells) At least 2 weeks away from previous radiotherapy and in general less than 25% of the bone marrow should be exposed. A patient with previously treated CNS metastasis is eligible only if there is no clinical or radiological evidence of CNS disease progression. Before starting the treatment, complete medical history and physical examination, measurement of height, weight, vital signs, pain score, ECOG score (this test indicates an increase in internal ear pressure in some patients), urine test, pregnancy test, Chest X-ray, ECG, serum biochemical testing including glucose and Cholesterol, electrolytes, urea, creatinine, complete blood count, liver function tests, and measuring tumor markers and VEGF and IL-6 have been done.

Exclusion criteria:

Ascites caused by other factors (e.g., kidney or heart failure, severe liver dysfunction / or occlusion of portal vein and peritoneal inflammation). Severe malnutrition or indigestion (with a BMI less than 19 kg / cm² and/or hypoproteinemia with serum albumin less than 20 g/ L). Inadequate blood function (Total neutrophil count less than 1500 / MM3 and platelet less than 100,000 / MM3). Severe infection requiring treatment. Coagulopathy or Encephalopathy. Other severe complications that are diagnosed by early examination, such as pregnancy or lactation or psychiatric disorders.

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked

No information

Sample sizeTarget sample size: **6**

More than 1 sample in each individual

Number of samples in each individual: **1**

In each participant, the volume of ascites will be measured and a sample of blood and a sample of ascites fluid will be taken before treatment with minocycline and after taking it every two weeks for two months totally five times.

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**

Research Department of the School of Medicine
Shahid Beheshti University of Medical Sciences

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Evin

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Approval date

2018-02-18, 1396/11/29

Ethics committee reference number

IR.SBMU. MSP.REC.1396.803

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

resistant malignant ascites

ICD-10 code

C78.6

ICD-10 code description

Secondary malignant neoplasm of retroperitoneum and
peritoneum, Malignant ascites NOS

Primary outcomes

1

Description

The volume of ascitic fluid, CA125, VEGF, IL-6

Timepoint

Once at the beginning, then every two weeks for two months

Method of measurement

Ultrasound + ascitic fluid and blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Minocycline Tablet with escalating dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Oncology department of Taleghani Hospital

Full name of responsible person

Dr. Tahereh Shirin Haghighi

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Oncology department, 4th floor, Taleghani Hospital, Shahid Arabi St., Daneshjoo Blvd., Evin.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant No 11708

Grant code / Reference number

کد ثبت 11708

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khojasteh Joharchi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data obtained from this study, except for the patient's profile, can be shared.

When the data will become available and for how long

Almost one year

To whom data/document is available

everyone

Under which criteria data/document could be used

Use of all the data is possible by mentioning the source.

From where data/document is obtainable

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What processes are involved for a request to access data/document

After a written request and after the necessary checks, they will be answered within a maximum of one week by email.

Comments