

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the Effect of ACA1 on the Quality of Life in Patients with Gastric adenocarcinoma: a pilot study

Protocol summary

Study aim

Evaluation of the effect of ACA1 product on quality of life, hematological and biochemical indicators of patients with gastric adenocarcinoma

Design

Two arm parallel group randomized clinical trial, double-blind, with 20 patients

Settings and conduct

This study is a double-blind clinical trial conducted as a pilot at Ayatollah Taleghani Hospital in Tehran. 20 patients after completing the standard questionnaire of quality of life of cancer patients EORTC-QLQ-30 and performing liver tests (PT-PTT-INR-ALP-AST-ALT) and kidney (urea -Cr) and complete counting of CBC blood cells entered the study and randomly divided into two groups of ten interventions and control and as a double-blind, intervention treatment group with ACA1 product at a dose of 2100 mg per day (three capsules). 670 mg, which is given three times a day for half an hour after a meal, is given for 1 month. The control group will also be treated daily with three placebo capsules according to the same instructions. Medication and placebo do not differ in weight, shape, color, odor, or taste. After 1 month, the standard EORTC-QLQ-30 questionnaire will be completed by patients. Patient Lab tests will be reviewed.

Participants/Inclusion and exclusion criteria

Admission: Patients with metastatic gastric adenocarcinoma
Lack of entry conditions: Positive serology for HIV, HBV, HCV, CNS metastasis, other malignancies

Intervention groups

Intervention group: treated with ACA1 product at a dose of 2100 mg per day for 1 month
Control group: daily treatment with placebo capsules three times a day for 1 month

Main outcome variables

Improving the quality of life; Improving laboratory tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200626047927N1**

Registration date: **2020-07-11, 1399/04/21**

Registration timing: **prospective**

Last update: **2020-07-11, 1399/04/21**

Update count: **0**

Registration date

2020-07-11, 1399/04/21

Registrant information

Name

Zahra Sharifan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

z.sharifan@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of ACA1 on the Quality of Life in Patients with Gastric adenocarcinoma: a pilot study

Public title

Evaluation of the Effect of ACA1 on Gastric adenocarcinoma:

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with gastric adenocarcinoma whose disease has been confirmed histologically, are in the metastatic stage and at least two common chemotherapy treatments have been administered to them and the disease is not under control. Adequate bone marrow function: $4000 < WBC < 12000$, Neutrophyl > 1500 , $Plt > 100000$, $Hb > 8$ Adequate liver function: Total Bill > 1.5 , $AST \& ALT < 100$ Adequate kidney function: $Cr < 1.5$ performance status ≤ 1

Exclusion criteria:

positive serology for HIV, HBV, HCV Metastasis to CNS other malignancies

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

The method of allocating samples in this study is stratified randomization. Initially, patients eligible for study based on gender and initial performance (according to the ECOG table) were divided into four groups (first group: male, 0 performance), (second group: male, 1 performance), (third group: female, 0 performance), (Group 4: female, 1 Performance) are divided. Patients in each group are then assigned to two groups of drugs and placebo based on a table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

A pharmacist at Shahed University Research Center prepares and codes the drug and placebo in such a way that they do not differ in weight, shape, color, odor or taste. He packs medicine and placebo in packs and gives them to the researcher. This person will not provide researchers with information about the samples until after the data analysis. All participants in this project and the clinical caregiver of the drug provider to the participants and the physician (the main researcher of the project) who is also responsible for data collection are unaware of the type of drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee on Biomedical Research of Shahed University

Street address

Shahed University, Persian Gulf Highway (Tehran - Qom), Tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2020-06-15, 1399/03/26

Ethics committee reference number

IR.SHAHED.REC.1399.039

Health conditions studied

1

Description of health condition studied

Gastric adenocarcinoma

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

Quality of Life

Timepoint

Start of study (before the start of the intervention) and one month after the start of ACA1 consumption

Method of measurement

EORTC-QLQ-30 Standard questionnaire

Secondary outcomes

1

Description

White Blood Cell Count

Timepoint

Start studying (before starting the intervention) and one month after starting ACA1 consumption

Method of measurement

Cell Counter

2

Description

Hemoglobin

Timepoint

Start studying (before starting the intervention) and one month after starting ACA1 consumption

Method of measurement

Cell Counter

3

Description

Platelet Count

Timepoint

Start studying (before starting the intervention) and one month after starting ACA1 consumption

Method of measurement

Cell Counter

4

Description

Body Mass Index

Timepoint

Start studying (before starting the intervention) and one month after starting ACA1 consumption

Method of measurement

Meter and scale

Intervention groups

1

Description

Intervention group: This group was treated with ACA1 capsules for 2100 mg per day for one month.

Category

Treatment - Drugs

2

Description

Control group: This group is treated with placebo capsules three times a day for a month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital

Full name of responsible person

Dr. Shirin Haghghi

Street address

Shahid Arabi Ave, Yaman Ave , Shahid Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

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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

Shahed University

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

Shahed University

Full name of responsible person

Zahra Sharifan

Position

Persian Medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Sharifan

Position

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information about the main outcome will be shared.

When the data will become available and for how long

The access period begins 6 months after publishing of results.

To whom data/document is available

It will be accessible to everyone.

Under which criteria data/document could be used

For scientific works with observing the principles of research ethics

From where data/document is obtainable

Zahra Sharifan, Mobile number: 00989125501170, Email: z.Sharifan@shahed.ac.ir, Address: No. 51, Golestan yak Ave, Pasdaran Ave, Tehran

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

Upon confirmation of the scientific identity of the Iranian questioner, he or she will be provided as soon as possible.

Comments