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
+98 21 2257 2759

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 Haghighi
Street address
Shahid Arabi Ave, Yaman Ave , Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
shirinhaghighi1346@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr. Zahra Kiasalari
Street address
Shahed university, Persian Gulf Highway (Tehran - Qom)
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 5106
Email
info@shahed.ac.ir
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

Street address
No.51, Golestan yek Ave, Pasdaran Ave

City
Tehran

Province
Tehran

Postal code
1666737133

Phone
+98 21 2257 2759

Email
z.Sharifan@shahed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Zahra Sharifan

Position
Persian Medicine resident

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Person responsible for updating data

Contact

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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
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 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