

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Diagnosing the prevalence of hidden peritoneal metastases of Gastric cancers by laparoscopy

Protocol summary

Study aim

Investigating and diagnosing the prevalence of occult peritoneal metastases in gastric cancer patients with laparoscopy

Design

Diagnostic study is performed without control group, single, phase 2 on 90 patients.

Settings and conduct

The study is performed in Sina Hospital on patients with gastric cancer to diagnosis hidden peritoneal metastases without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Existence of confirmed gastric cancer in tissue biopsy, And in histological examinations T3 or higher, The exact stage of the disease is diagnosed by CT scan with or without endosonography
Exclusion criteria: Existence of metastases proven in histological or radiological examinations, Presence of tissue metastasis during surgery, Clear seeding to the peritoneum during surgery, Existence of any contraindications for diagnostic laparoscopy, History of receiving any radiotherapy or adjuvant chemotherapy

Intervention groups

All patients with gastric cancer who met the inclusion criteria under general anesthesia underwent diagnostic laparoscopic surgery. At the beginning of surgery, the entire abdomen, is examined with a 30-degree camera and if there is free fluid in the abdominal space, this fluid will be sampled. In the absence of free fluid in the abdomen, serous levels in the abdomen and stomach are lavaged with 100 cc of normal saline and then the lavaged fluid is aspirated and sent for cytological examination. Four samples of peritoneal tissue are sent to detect metastasis.

Main outcome variables

intra-operative T Staging, Intra-operative N Staging, Peritoneal involvement, Positive cytology

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180720040533N2**

Registration date: **2022-07-10, 1401/04/19**

Registration timing: **prospective**

Last update: **2022-07-10, 1401/04/19**

Update count: **0**

Registration date

2022-07-10, 1401/04/19

Registrant information

Name

Farzad Vaghef Davari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 5448

Email address

fvdavari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Diagnosing the prevalence of hidden peritoneal metastases of Gastric cancers by laparoscopy

Public title

Diagnosis of hidden peritoneal metastases in gastric cancers

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of confirmed gastric cancer in tissue biopsy
The tumor is T3 or higher on histological examination
The exact stage of the disease is diagnosed by CT scan with or without endosonography
Patients aged 20-75 years

Exclusion criteria:

Existence of metastases proven in histological or radiological examinations
Presence of tissue metastasis during surgery
Clear seeding to the peritoneum during surgery
Intolerance to general anesthesia
Existence of any contraindications for diagnostic laparoscopy
History of receiving any radiotherapy or adjuvant chemotherapy before diagnostic laparoscopy

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

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 in Research of Imam Khomeini Hospital Complex

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, At the end of Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۳۴

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.058

Health conditions studied

1

Description of health condition studied

Gastric cancer

ICD-10 code

C16.9

ICD-10 code description

Malignant neoplasm of stomach, unspecified

Primary outcomes

1

Description

The result of sampling from omentum

Timepoint

one time and 10 days after biopsy

Method of measurement

Based on biopsy results

2

Description

The result of cytology of free fluid or abdominal lavage fluid

Timepoint

one time, 10 days after drawing the liquid

Method of measurement

Based on the pathology result

3

Description

Presence of ascites during surgery

Timepoint

Once and at the beginning of surgery

Method of measurement

Direct observation during surgery

4

Description

Depth of penetration of tumor tissue in adjacent tissue layers

Timepoint

Once during surgery

Method of measurement

Direct observation during surgery

5

Description

Extent of adjacent or distant lymph nodes involved by tumor tissue

Timepoint

Once during surgery

Method of measurement

Direct observation during surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At the beginning of the laparoscopy, the entire abdominal area, including the stomach, peritoneum, omentum, pelvis, and liver, is examined with a 30-degree camera, and if there is free fluid in the abdomen, the fluid will be sampled. In the absence of free fluid in the abdomen, Serous viscera in the abdomen and stomach are lavaged with 100 cc of normal saline and then the lavage fluid is aspirated and sent for cytological examination. Then all the peritoneum is examined and if there is any lesion suspected of metastasis in the mentioned areas, a biopsy lesion is performed and a sample is sent for pathological examination.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Sinai Hospital

Full name of responsible person

Farzad Vaghef Davari

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Sina hospital, Hasan Abad Sq-Emam khomeini st.

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: Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotuhi

Street address

Central Organization of Tehran University of Medical Sciences of Tehran, Corner of Quds St., Keshavarz Blvd

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1417653761

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Farzad Vaghef Davari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Cancer Institute, Imam Khomeini Hospital, Keshavarz Blvd., Tehran

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Person responsible for scientific inquiries

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Position

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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

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published as an article

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Academic researcher groups

Under which criteria data/document could be used

Share experiences

From where data/document is obtainable

Dr. Farzad vaghef Davari

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

One month after receiving the email

Comments

Email address: fvdavari@sina.tums.ac.ir