Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Th 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 adjutant 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
Street address
Sina hospital,Hasan Abad Sq-Emam khomeni 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 Organizatioehran University of Medical Sciences of Tehran,Corner of Quds St.,Keshavarz Blvd
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Postal code
1417653761
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+98 21 8163 3698
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vcr@tums.ac.ir
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

Contact

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Position
Assistant professor

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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
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
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