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Can the value of the tumor biomarker CA-125 divided by the value of the tumor biomarker CEA help in the diagnosis of ovarian cancer in women with pelvic cancer?

Submission date
15/02/2024

Recruitment status
No longer recruiting

Registration date
16/02/2024

Overall study status
Completed

Last Edited
04/03/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Carbohydrate antigen 125 (CA-125) is a serum tumor marker useful in the follow-up and to detect the recurrence or even the presence of residual ovarian cancer when associated with imaging tests. However, its isolated use is limited for early diagnosis or differential diagnosis of ovarian cancer. Some studies suggest that in the presence of above-normal serum CA-125 levels in non-ovarian cancer patients, a serum CA-125/CEA ratio could confirm non-ovarian cancer. This study aims to find out whether their ratio (CA-125/CEA) can help in the differential diagnosis between ovarian cancer and other neoplasms in the lower abdomen and/or metastases.

Who can participate?
Women who have a mass in the lower part of the abdomen, or metastases in the peritoneum (a type of skin that surrounds most of the organs in the abdomen) and/or ascites (accumulation of fluid in the abdomen).

What does the study involve?
The study involves measuring two tumor biomarkers, CA-125 and CEA, and a tumor pathology exam.

What are the possible benefits and risks of participating?
This is a study with minimal risk for the participants, such as the possible breach of patient data confidentiality. Furthermore, this study does not assess oncological outcomes, but diagnoses. However, the researchers have undertaken not to disclose this data and to maintain total confidentiality. This study may not bring any immediate benefit to the research participant, but it may show possible future benefits for other patients.

Where is the study run from?
Barretos Cancer Hospital (Brazil)

When is the study starting and how long is it expected to run for?
October 2015 to September 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Jeferson Rodrigo Zanon, jeferson.zanon@hcancerjales.com.br, jrzanon@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Jeferson Zanon

ORCID ID
https://orcid.org/0000-0003-2074-1829

Contact details
Avenida Francisco Jalles, 3737
Jales
Brazil
15706-396
+55 (0)17 3624 3900
jeferson.zanon@hcancerjales.com.br

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Can CA-125/CEA ratio be used for the differential diagnosis between ovarian and non-ovarian cancers? A diagnostic cross-sectional retrospective study

Study objectives
Is CA-125/CEA ratio a diagnostic tool for the differential diagnosis between ovarian cancer and other advanced intra-abdominal neoplasms?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/04/2016, Research Ethics Committee of the Pio XII Foundation - Barretos Cancer Hospital (Rua Antenor Duarte Vilela, 1331, Barretos, 14784-400, Brazil; +55 (0)17 3321 0347; cep@hcancerbarretos.com.br), ref: 54129515.8.0000.5437

Study design
Diagnostic cross-sectional retrospective study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Ovarian cancer, other intra-abdominal neoplasms

Interventions
A diagnostic cross-sectional retrospective study is performed in patients with pelvic mass, peritoneal carcinomatosis and/or ascites and initial suspicion of ovarian malignancy. All patients have serum CA-125, CEA and biopsy. CA-125/CEA cutoffs for ovarian/non-ovarian cancer are determined using ROC curves to determine the best sensitivity and specificity. Population adjustment is performed using propensity score matching (PSM).

Intervention Type
Other

Primary outcome(s)
Receiver operating characteristic (ROC) curves to determine the cut-off values for CA-125/CEA ratio in the participants, comparing ovarian cancer with non-ovarian cancer, gastrointestinal cancer, and colorectal cancer, followed by a performance characteristic test to determine sensitivity, specificity, positive predictive value, accuracy (all ovarian cancer positive cases divided by the participants), type I error, 1, and 2 (the power of the test), positive predictive value, negative predictive value, accuracy (all ovarian cancer positive cases divided by all participants), type I error, 1 minus type II error (the power of the test), positive and negative likelihood ratios with pathology findings as the gold standard (chi-squared test or Fisher's test). Measured at a single timepoint.

Key secondary outcome(s))
The same as the primary outcome measure but after propensity score matching analysis (PSM)

Completion date
23/09/2018

Eligibility

Key inclusion criteria

Patients with a pelvic mass, peritoneal carcinomatosis and/or ascites

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
Female

Total final enrolment
338

Key exclusion criteria
1. Previous surgery at another service
2. If the pathology results showed benign lesions
3. If the sample was insufficient for a definitive diagnosis
4. If no biopsy was performed

Date of first enrolment
21/04/2016

Date of final enrolment
20/08/2018

Locations

Countries of recruitment
Brazil

Study participating centre
Barretos Cancer Hospital
Rua Antenor Duarte Vilela, 1331
Barretos
Brazil
14784-400

Sponsor information

Organisation
Hospital de Câncer de Barretos

ROR
https://ror.org/00f2kew86

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Jeferson Rodrigo Zanon (jeferson.zanon@hcancerjales.com.br, jrzanon@hotmail.com).
The type of data that will be shared: SPSS data bank.
Dates of availability: Indefinitely
This study was approved by the local institutional review board (number 54129515.8.0000.5437), and a waiver of informed consent was granted.
The database consists of patient information with a personal identifier. This data is stored on the REDCap Platform, which is among the best data collection, management and storage platforms for research and multi-institutional studies. It complies with the American laws on the protection of patient data, the Health Insurance Portability and Accountability Act (HIPAA). In addition to secure data storage and management, research data is stored on the institution's own server.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/08/2024	04/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes