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Identifying factors contributing to poor outcomes in patients with gastric cancer.

Submission date 12/03/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/03/2019	**Overall study status** Completed	
Last Edited 24/09/2021	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Gastric cancer (GC) is the second leading cause of cancer-related mortality worldwide. Therefore, identifying the predictive factors for surgical morbidity, disease recurrence, and long-term survival is necessary for preventing GC patient mortality. We aimed to evaluate the factors that contribute to the poor prognoses of GC patients.

Who can participate?
All post-curative resection gastric cancer patients.

What does the study involve?
All patients underwent total or distal gastrectomy, and we gave chemotherapy to the patient whom a state has good.

What are the possible benefits and risks of participating?
No benefits and risks of participating.

Where is the study run from?
Onomichi General Hospital

When is the study starting and how long is it expected to run for?
May 2011 to June 2017.

Who is funding the study?
Investigator-initiated and funded.

Who is the main contact?
Hitomi Takechi, red.df2fb@gmail.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Study information

Scientific Title
Using the preoperative prognostic nutritional index as a predictive factor for non-cancer-related death in post-curative resection gastric cancer patients: a retrospective study

Acronym
GC, PNI

Study objectives
We aimed to evaluate the factors that contribute to the poor prognoses of gastric cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2019, Ethical Review Board of Onomichi General Hospital (1-10-23, Hirahara, Onomichi-shi, Hiroshima, 722-8508, Japan; +81-848-22-8111), ref: OJH-201892.

Primary study design
Observational

Study design
Retrospective, single-centre, observational, longitudinal study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Gastric adenocarcinomas

Interventions
All patients underwent total or distal gastrectomy and D1+ or D2 lymph node dissection in accordance with the Japanese Gastric Cancer Treatment Guidelines published in 2010 (ver. 3). All patients were histologically confirmed to have stage I, II, or III gastric adenocarcinomas and

underwent total or distal gastrectomy. The total duration of observation and follow-up were conducted within 5 years post-operation, or until death.

Intervention Type
Other

Primary outcome(s)
1. Disease-free survival is defined as the time between the date of surgery and disease recurrence or the last available follow-up.
2. Overall survival is defined as the time between the date of surgery and death or the last available follow-up.

Key secondary outcome(s)
1. Absolute neutrophil and lymphocyte counts are measured using routine blood and biochemical tests on the day before surgery.
2. Serum albumin is measured using routine blood and biochemical tests on the day before surgery.
3. C-reactive protein (CRP) concentrations are measured using routine blood and biochemical tests on the day before surgery.
4. Prognosis is measured using the modified Glasgow Prognosis Score, perineural invasion and neutrophil to lymphocyte ratio on the day before surgery.
5. Diagnosis is determined using surgical pathology reports after surgery.

Completion date
30/06/2017

Eligibility

Key inclusion criteria
Post-curative resection gastric cancer patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
182

Key exclusion criteria
N/A

Date of first enrolment

14/12/2016

Date of final enrolment
15/05/2017

Locations

Countries of recruitment
Japan

Study participating centre
Department of Surgery, Onomichi General Hospital
1-10-23, Hirahara, Onomichi-shi
Hiroshima
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722-8508

Sponsor information

Organisation
Department of Surgery, Onomichi General Hospital

ROR
https://ror.org/05nr3de46

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 are/will be available upon request from Hitomi Takechi (red.df2fb@gmail.com). The data will be available for 5 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/08/2020	24/09/2021	Yes	No