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

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

Study website
N/A

Contact information

Type(s)
Public

Contact name
Dr Hitomi Takechi

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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.

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

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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.

Secondary outcome measures
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.

Overall study start date
09/05/2011

Completion date

30/06/2017

Eligibility

Key inclusion criteria
Post-curative resection gastric cancer patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
182 patients

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
Japan
722-8508

Sponsor information

Organisation
Department of Surgery, Onomichi General Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://onomichi-gh.jp/

ROR
https://ror.org/05nr3de46

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in BMC Gastroenterology.

Intention to publish date
31/03/2019

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