

Prognostic significance of HER2 expression in patients with resectable gastric cancer

Submission date 23/08/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/09/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/09/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

Background and study aims

The aim of this study is to investigate the relationship between human epidermal growth factor receptor 2 (HER2) overexpression and clinicopathologic factors and survival rate in patients who underwent curative gastrectomy (removal of part or all of the stomach) as treatment for gastric adenocarcinoma (stomach cancer).

Who can participate?

Patients who underwent curative gastrectomy to treat gastric adenocarcinoma at Inje University Paik Hospital over four years, from January 2012 to December 2015

What does the study involve?

HER2 expression levels measured and clinicopathologic records are collected from a gastric cancer database to identify clinicopathologic features and survival rates of the patients.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Inje University Busan Paik Hospital (China)

When is the study starting and how long is it expected to run for?

March 2017 to January 2018

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof. Kwang-Hee Kim

Contact information

Type(s)

Public

Contact name

Prof KwangHee Kim

Contact details

Bokji-ro 75, Busangjin-gu

Busan

Korea, South

47392

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Prognostic significance of HER2 expression in patients with resectable gastric adenocarcinoma

Study hypothesis

The purpose of this study was to investigate HER2 overexpression by immunohistochemical (IHC) analysis in gastric adenocarcinoma tissues that were obtained by curative gastrectomy. In addition, the trialists compared clinicopathologic factors and survival rates according to HER2 expression level to identify factors associated with HER2 overexpression. Furthermore, HER2 overexpression was examined to determine its value as an independent prognostic factor.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board at the Inje University Busan Paik Hospital, 24/07/2017, IRB No. 17-0104

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Condition**

Gastric adenocarcinoma

Interventions

Among patients who underwent curative gastrectomy to treat gastric adenocarcinoma at Inje University Paik Hospital over four years, from January 2012 to December 2015, 782 patients underwent an immunohistochemical analysis to evaluate HER2 expression levels. Clinicopathologic records that were collected from a gastric cancer database were retrospectively reviewed to identify clinicopathologic features and survival rates of the patients.

Intervention Type

Genetic

Primary outcome measure

HER2 overexpression measured by immunohistochemical (IHC) analysis in gastric adenocarcinoma tissues obtained by curative gastrectomy at baseline

Secondary outcome measures

Clinicopathologic factors and survival rates collected from a gastric cancer database at August 2017

Overall study start date

01/03/2017

Overall study end date

30/01/2018

Eligibility**Participant inclusion criteria**

Among 810 patients who underwent curative gastrectomy to treat gastric adenocarcinoma at Inje University Busan Paik Hospital over four years, from January 2012 to December 2015, this study included 782 patients after excluding 28 patients who did not undergo IHC analysis

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

782

Participant exclusion criteria

Does not meet inclusion criteria

Recruitment start date

01/01/2012

Recruitment end date

31/12/2015

Locations

Countries of recruitment

Korea, South

Study participating centre

Inje University Busan Paik Hospital

Bokji-ro 75, Busangjin-gu

Busan

Korea, South

47392

Sponsor information

Organisation

Inje University Busan Paik Hospital

Sponsor details

Bokji-ro 75, Busangjin-gu

Busan

Korea, South

47392

+82 (0)518906114

inwoodog@naver.com

Sponsor type

Hospital/treatment centre

Website

<http://www.paik.ac.kr/busan/>

ROR

<https://ror.org/01pzf6r50>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Kwang-Hee Kim. Surgeons perform gastrectomy and collect personal data. Then, if necessary, manually extract and use the data. So when you ask for data, it is possible to verify that the patient is not identified. The individual has all the data but there is no formalized program. Data is stored on a personal computer. It may be disclosed on demand. However, it is not considered easy to use the data as it is not intended to identify the patient.

IPD sharing plan summary

Available on request