

# Prognostic significance of HER2 expression in patients with resectable gastric cancer

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

## Plain English summary of protocol

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 objectives**

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****Health condition(s) or problem(s) studied**

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

**Completion date**

30/01/2018

**Eligibility****Key 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

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/01/2012

**Date of final enrolment**

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