

# Does add-on therapy with Chinese herb medicine Bo-Er-Ning capsule (BENC) improve the outcomes of gastric cancer patients?

<b>Submission date</b> 09/03/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/03/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Bo-Er-Ning capsule (BENC) is a traditional Chinese medicine derived from natural products. It is composed of a series of key pharmaceutical ingredients, including Radix Astragali, Fructus Ligustri Lucidi, Tulipaedulis, Herba Portulacae, Rhizoma Paridis, Solanum Nigrum, Fructus Perillae, Corium Stomachichum galli, Rhubarb, Borneol and Bombyx Batryticatus. The aim of this study is to assess the effect of BENC on gastric (stomach) cancer patients.

### Who can participate?

Patients aged 25 to 75 with gastric cancer

### What does the study involve?

Participants are randomly allocated into two groups: the trial group and the control group. The trial group receive BENC accompanying tegafur and cisplatin drug treatment, while the control group receive tegafur and cisplatin only. Both groups are assessed after three cycles of treatment (each cycle involves 14 days of treatment and 7 days of rest).

### What are the possible benefits and risks of participating?

Patients from the trial group may have a better quality of life, such as better appetite and body weight gain, and improved overall survival. As a typical Chinese herb medicine, BENC has been used as an additional medicine for other types of cancer, and no side effects have been reported.

### Where is the study run from?

Zhangqiu People's Hospital of Shandong (China)

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

January 2008 to June 2012

### Who is funding the study?

Zhangqiu People's Hospital of Shandong (China)

Who is the main contact?

Prof. Jie He

## Contact information

### Type(s)

Scientific

### Contact name

Prof Jie He

### Contact details

Zhangqiu People's Hospital of Shandong

Jinan

China

250200

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2-3-84

## Study information

### Scientific Title

Evaluation of the adjuvant therapeutic efficacy of Bo-Er-Ning capsule (BENC) in advanced gastric cancer patients by a randomized clinical trial

### Study objectives

The addition of BENC to chemotherapy is better than chemotherapy alone.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics board of Zhangqiu People's Hospital of Shandong, 04/03/2008, ref: ZQH/2008/03-1

### Study design

Single-centre randomized controlled trial

### Primary study design

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Advanced gastric cancer

**Interventions**

All patients with advanced GC treated by FP regimen (Tegafur + Cisplatin) in Zhangqiu People's Hospital of Shandong were enrolled for this clinical study by a doctor participating in the study and randomly divided into two groups by another doctor. Among those, 58 patients received BENC accompanying FP regimen (trial group), while 54 patients received FP regimen alone (control group).

Treatment regimen for control group: Tegafur 40~60mg, oral administration, two times a day, from day 1 to day 14 and Cisplatin 40mg, intravenous infusion administration, from day 1 to day 3.

Treatment regimen for trial group: BENC 4 capsules, taken orally three times a day (with warm water half an hour after a meal) for 14 days (from day 1 to day 14), accompanying Tegafur and Cisplatin treatment (the same drug dosage and usage as the control group).

Both groups were evaluated after 3 cycles (both groups take 21 days as one cycle) of chemotherapy (14 days of treatment and 7 days of rest).

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Tegafur, cisplatin, Bo-Er-Ning capsule

**Primary outcome measure**

Measured at week 9 (after 3 cycles of chemotherapy):

1. Appetite, assessed by filling out answer sheets
2. Karnofsky performance score (KPS), assessed by filling out answer sheets
3. Body weight, measured using a weight scale

**Secondary outcome measures**

3-year overall survival: patients followed up by clinic visit, phone, or mail at least once every 6 months starting from day 1 after the treatment

**Overall study start date**

01/01/2008

**Completion date**

30/06/2012

## **Eligibility**

**Key inclusion criteria**

1. Age from 25 to 75 years
2. All patients were pathologically confirmed for stage IV or postoperative recurrence and metastasis GC
3. Karnofsky performance score (KPS)  $\geq$  80
4. No previous anticancer therapy
5. No dysfunction of heart, liver, lung and kidney

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Trial group: 60; control group: 60

**Key exclusion criteria**

1. Age < 25 and > 75 years
2. Patients were not pathologically confirmed for stage IV or postoperative recurrence and metastasis GC
3. Karnofsky performance score (KPS) < 80
4. Possess previous anticancer therapy
5. Possess dysfunction of heart, liver, lung and kidney

**Date of first enrolment**

15/03/2008

**Date of final enrolment**

15/09/2008

## **Locations**

**Countries of recruitment**

China

**Study participating centre**  
Zhangqiu People's Hospital of Shandong  
China  
250200

## Sponsor information

**Organisation**  
Zhangqiu People's Hospital of Shandong

**Sponsor details**  
1920 Huiquan Road  
Zhangqiu District  
Jinan  
China  
250200

**Sponsor type**  
Hospital/treatment centre

**ROR**  
<https://ror.org/00fts7a69>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Zhangqiu People's Hospital of Shandong

## Results and Publications

**Publication and dissemination plan**  
Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available to protect the privacy of the patients.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2018		Yes	No