

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

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Zhangqiu People's Hospital of Shandong

Results and Publications

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?
Results article	results	01/06/2018		Yes	No