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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

Registration date
24/03/2018

Overall study status
Completed

Last Edited
17/01/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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) ≥ 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?
Results article	results	01/06/2018		Yes	No