

Symptom relief by traditional Chinese medicine at a Chinese medicine ward for head and neck cancer patients undergoing radiotherapy

Submission date 26/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/05/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to investigate whether treatment with both traditional Chinese medicine and Western medicine alleviates the side effects of radiation treatment in head and neck cancer patients. This may help cancer patients to complete their treatment and improve their quality of life.

Who can participate?

Patients aged from 20 to 75, diagnosed with head and neck cancer, who are going to receive radiotherapy with or without chemotherapy.

What does the study involve?

The study group are admitted to the Chinese medicine ward of Chang Gung Memorial Hospital, Taoyuan, Taiwan, and receive integrated treatment of traditional Chinese medicine from the first week of radiotherapy till the end. The control group only receive conventional cancer treatment at the Radio-Oncology or Oncology outpatient department.

What are the possible benefits and risks of participating?

Participants in the study group may experience fewer side effects and better quality of life compared with conventional cancer treatment. There were no known side effects related to the Chinese medicine used in our ward.

Where is the study run from?

Chang Gung Memorial Hospital, Linkou, and Taoyuan branch (Taiwan)

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

February 2013 to January 2015

Who is funding the study?

Chang Gung Memorial Hospital (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The efficacy of integrated traditional Chinese medicine intervention at a Chinese medicine ward for head and neck cancer patients undergoing radiotherapy

Study objectives
Integrated traditional Chinese medicine intervention may reduce symptoms caused by radiation and provide better quality of life for head and neck cancer patients

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Interventional non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Acute toxicities post radiotherapy for head and neck cancers

Interventions

Patients choose to be in the study group or the control group according to their wishes. The study group are admitted to the Chinese medicine ward, Chang Gung Memorial Hospital, Taoyuan, Taiwan, and receive integrated treatment of traditional Chinese medicine from the first week of radiotherapy till the end. The control group only receive conventional cancer treatments at the Radio-Oncology or Oncology outpatient department.

Both the study group and the control group receive conventional cancer therapy as surgery, radiation therapy or chemotherapy according to their disease status as usual.

Intervention Type

Other

Primary outcome measure

1. EORTC QLQ – H&N35 once per week since the second week of radiotherapy till the end
2. RTOG acute radiation morbidity scoring criteria measured at the first week, the fourth week and the end of radiotherapy

Secondary outcome measures

1. EORTC QLQ-C30 (version 3.0) measured at first, second, fourth and the end of radiotherapy
2. Body Constitution Questionnaire measured at first, second, fourth and the end of radiotherapy
3. Body weight per week since the first week of radiotherapy till the end
4. CBC/DC, AST, ALT, BUN, Cr, Albumin, High-sensitivity CRP, SCC of hospitalized patients at the beginning and the end of traditional Chinese medicine intervention

Overall study start date

01/02/2013

Completion date

20/01/2015

Eligibility

Key inclusion criteria

1. Patients aged from 20 to 75 years old diagnosed with head and neck cancer and receiving radiotherapy with or without chemotherapy
2. Stable vital signs
3. Eastern Cooperative Oncology Group (ECOG) 0-2

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60 for study group and 60 for control group

Total final enrolment

131

Key exclusion criteria

1. Cancer in terminal stage when aggressive treatments are not suitable
2. Unstable vital signs
3. ECOG performance 3
4. Impaired renal and liver function at initial diagnosis (including chronic kidney disease stage III, IV, V and AST, ALT 5upper normal limit)
5. Patients who have uncontrolled psychiatric problems or unclear consciousness
6. Patients who are receiving other Chinese medicine treatments

Date of first enrolment

11/03/2013

Date of final enrolment

19/12/2014

Locations

Countries of recruitment

Taiwan

Study participating centre
Chang Gung Memorial Hospital, Linkou, and Taoyuan branch
Taiwan
886

Sponsor information

Organisation
Chang Gung Memorial Hospital (Taiwan)

Sponsor details
123, Dinghu Rd
Jiolu Village
Gueishan Township
Taoyuan
Taiwan
333/886

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/02verss31>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Memorial Hospital (Taiwan)

Results and Publications

Publication and dissemination plan
Currently we are preparing for submission of the paper to a journal

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2016	29/05/2020	Yes	No