

A cancer rehabilitation and lymphedema care program for patients with resected advanced head and neck cancer

Submission date 17/10/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/06/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Swelling of the face or neck (lymphoedema) can occur after treatment for head and neck cancer. The aim of this study is to examine the effects of a 6-month Cancer Rehabilitation and Lymphedema Care Program (CRLCP) on lymphoedema-related symptoms, body image and functional outcomes.

Who can participate?

Patients aged 20 to 70 with head and neck cancer-related lymphoedema (HNCRL)

What does the study involve?

Participants are recruited three months after the completion of treatment and randomly allocated into either the control group (who receive routine hospital care) or the experimental group (who receive the 6-month CRLCP). Symptoms, body image and functional outcomes are assessed before the CRLCP and 1, 3, and 6 months after first participating in the CRLCP.

What are the possible benefits and risks of participating?

If the CRLCP is effective, a scientific program will be developed based on the CRLCP intervention to improve HNCRL-related symptoms, body image and functional outcomes among Taiwanese patients with head and neck cancer. This study does not involve any invasive intervention. Cancer rehabilitation with lymphoedema care has been demonstrated to be a safe means of managing lymphedema. Before beginning the program, patients undergo an evaluation of their skin integrity. If any participant develops skin defects or a skin infection, they are referred to their attending physician for treatment.

Where is the study run from?

Linkou Chang Gung Hospital (Taiwan)

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

January 2016 to December 2019

Who is funding the study?
Ministry of Science and Technology (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MOST105-2628-B-255-001-MY3

Study information

Scientific Title

A cancer rehabilitation and lymphedema care program for patients with resected advanced head and neck cancer: the prevalence and risk factors for head and neck cancer-related lymphedema and development and testing of an intervention and longitudinal measures of its functional outcomes

Acronym

CRLCP

Study objectives

The prevalence of HNCRL and the risk factors for HNCRL in head and neck cancer patients post-treatment have not yet been examined. A Cancer Rehabilitation and Lymphedema Care Program can prevent the progression of adverse effects, decrease functional impairment, and maximize functional ability in these patients. According to official reports on cancer rehabilitation and lymphedema care, and a previous study, a Cancer Rehabilitation and Lymphedema Care Program (CRLCP) significantly helps patients cope with HNCRL-related symptoms, improved body image, and increase HNCRL-related functional outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Institutional Review Board of Chang Gung Memorial Hospital, Taiwan, 19/01/2016, ref: 104-8655B

Study design

Prospective randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Head and neck cancer

Interventions

Eligible participants will be recruited three months after the completion of treatment and randomized by casting lots for odd or even numbers (even-control, odd-experimental) into a control group (who will receive routine hospital care) and an experimental group (who will receive the 6-month Cancer Rehabilitation and Lymphedema Care Program (CRLCP)).

Subjective and objective data will be collected at four time points: baseline (before the CRLCP) (T0) and 1, 3, and 6 months after first participating in the CRLCP (T1, T2, and T3, respectively). Mixed-model analysis will be used to assess the effectiveness of the intervention program on patients' HNCRL-related symptoms, body image, and HNCRL-related functional outcomes.

Intervention Type

Behavioural

Primary outcome(s)

Functional outcomes measured by the Brief International Classification of Functioning, Disability and Health (ICF) Core Set for Head and Neck Cancer (BCSQ-H&N) at four time points: baseline (before the CRLCP) (T0) and 1, 3, and 6 months after first participating in the CRLCP (T1, T2, and T3, respectively)

Key secondary outcome(s)

Measured at four time points: baseline (before the CRLCP) (T0) and 1, 3, and 6 months after first participating in the CRLCP (T1, T2, and T3, respectively):

1. Symptom distress measured by the Symptom Distress Scale–Modified for Head and Neck Cancer (SDS-mhnc)
2. Body image measured by the Body Image Scale–Modified (BIS-m)
3. Stage of lymphedema measured by the MD Anderson Head and Neck Lymphedema Rating Scale (MDAHNLRs)
4. Shoulder motion measured by the UCLA Shoulder Rating Scale (UCLA SRS)
5. Physical performance measured by the Karnofsky Performance Status Index (KPS)

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Pathologic confirmation of advanced HNSCC (stage III or IV) and patient awareness of the diagnosis
2. Receipt of radical surgery and RT or CCRT
3. Completion of radical surgery and RT or CCRT from 3 months to 5 years in the past
4. Have HNCRL based on physical examination (Foldi's Scale score > stage I)
5. Currently free of evidence of cancer
6. Age greater than 20 years and less than 70 years
7. Karnofsky's Performance Status Index (KPS) score of 60 or greater
8. Agreement to participate in the study after explanation of its purposes and procedures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Unresected head and neck cancer
2. Actively undergoing chemotherapy or RT
3. Having metastatic cancer or any other active cancer
4. Any unstable systemic disease (heart disease, active infection, or other underlying disease)
5. KPS score of 60 or less
6. Any condition likely to cause discomfort during the research interview

Date of first enrolment

01/08/2017

Date of final enrolment

31/07/2019

Locations

Countries of recruitment

Taiwan

Study participating centre

Linkou Chang Gung Hospital

5, Fu Hsing Street, Kweshian

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Sponsor information

Organisation

Ministry of Science and Technology, Taiwan

ROR

<https://ror.org/02kv4zf79>

Funder(s)

Funder type

Government

Funder Name

Ministry of Science and Technology, Taiwan (MOST105-2628-B-255-001-MY3)

Alternative Name(s)

Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Taiwan

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.

IPD sharing plan summary

Not expected to be made available