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# Axillary–lateral thoracic vessel juncture sparing and 2-year breast cancer–related lymphedema after postmastectomy radiotherapy: a prospective nonrandomized concurrently controlled study

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| **Submission date**<br>11/11/2026 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>12/11/2026 | **Overall study status**<br>Completed | |
| **Last Edited**<br>12/11/2026 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Principal investigator, Scientific, Public

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## Additional identifiers

## Study information

## Scientific Title
A randomized non-inferiority clinical study on the effect of axillary organ-at-risk sparing during postmastectomy radiotherapy on breast cancer–related lymphedema

## Study objectives

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 21/07/2023, Changshu No.1 People's Hospital Ethics Committee (Shuyuanjie 1st, Changshu, 215500, China; +86 512 52223969; no email provided), ref: X2023033

## Primary study design
Interventional

## Allocation
Non-randomized controlled trial

## Masking
Open (masking not used)

## Control
Dose comparison

## Assignment
Parallel

## Purpose
Treatment

## Study type(s)

## Health condition(s) or problem(s) studied
Prevention of breast cancer-related lymphedema in patients undergoing radical mastectomy who receive postoperative radiotherapy

## Interventions
Patients were assigned to conventional or ALTJ-sparing planning using a prespecified alternating sequence. Allocation was deterministic and nonrandom.
In the conventional group, the ALTJ was delineated for dosimetric analysis but excluded from optimization. In the ALTJ-sparing group, ALTJ V30 ≤50% was added as a planning objective. Planning target volume (PTV) coverage and conventional OAR constraints, particularly for the heart and lungs, took priority, and the ALTJ objective could be relaxed when necessary.
Both groups received identical postoperative rehabilitation exercises and BCRL-prevention education. Bilateral arm circumferences were measured 5 and 15 cm above and 10 cm below the olecranon before radiotherapy, immediately after completion (month 0), and every 3 months thereafter. BCRL required a baseline-adjusted increase of ≥2 cm in the affected-minus-contralateral arm circumference difference at any site, confirmed at the next visit.

### Intervention Type
Behavioural

### Primary outcome(s)
1. The cumulative incidence of Bilateral arm circumferences measured using tape measure at 5 and 15 cm above and 10 cm below the olecranon at immediately after completion (month 0), and every 3 months thereafter

### Key secondary outcome(s)
1. ALTJ dosimetric parameters, and differences in PTV coverage, CI, HI, and dosimetric parameters for conventional OARs, including the heart and lungs. measured using data extracted from the treatment planning system at after radiotherapy

### Completion date
30/09/2026

## Eligibility

### Key inclusion criteria
1. Female sex
2. Age <80 years
3. Karnofsky Performance Status (KPS) >80
4. Histologically confirmed invasive breast cancer treated with modified radical mastectomy
5. An indication for postoperative regional radiotherapy, including a primary tumor >5 cm, ≥4 positive axillary lymph nodes, or T1-2 disease with 1-3 positive axillary lymph nodes accompanied by high-risk features, such as <10 axillary lymph nodes retrieved, lymphovascular invasion, triple-negative breast cancer, or age <35 years
6. No contraindication to radiotherapy
7. No evidence of upper-extremity lymphedema before radiotherapy
8. The ability to understand and comply with the scheduled follow-up and upper-extremity measurements

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
34 Years

### Upper age limit
78 Years

### Sex
Female

### Total final enrolment
110

### Key exclusion criteria
1. Had a history of ipsilateral upper-extremity lymphedema or preexisting upper-extremity swelling before radiotherapy
2. Another concurrent malignancy
3. Bilateral breast cancer
4. Were considered unlikely to complete the prescribed treatment or scheduled follow-up

### Date of first enrolment
21/07/2023

### Date of final enrolment
30/06/2024

## Locations

### Countries of recruitment
China

## Sponsor information

### Organisation
Changshu No.1 People's Hospital

### ROR
https://ror.org/032hk6448

## Funder(s)

### Funder type

### Funder Name
2023 Changshu Health Commission Science and Technology Plan Sponsored Projects and Changshu Science and Technology Development Plan (Medical and Health) Guidance Projects (CSWS202304)

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

### IPD sharing plan summary
Published as a supplement to the results publication