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Testing a new rehabilitation belt to help patients walk early after chest surgery

Submission date	Recruitment status	[_] Prospectively registered
20/08/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/08/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/08/2026	Surgery	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Mrs Qiuxia Liu

Contact details
No. 181 Hanyu Road, Shapingba District
Chongqing
China
400030
+86 (0)17382937847
471519103@qq.com

Additional identifiers

Study information

Scientific Title
The design and clinical application of a multifunctional rehabilitation belt for early ambulation after thoracic surgery: a cluster randomized controlled trial

Study objectives
To design a multifunctional rehabilitation belt and evaluate its clinical efficacy in promoting early ambulation in patients after thoracic surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 15/05/2024, Ethics Committee of Chongqing University Cancer Hospital (Department of Thoracic Oncology, No. 181 Hanyu Road, Chongqing, 400030, China; +86 (0)23 65075696; liuqiuxia@edu.com), ref: CZLS2024252-A-19

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Postoperative recovery after video-assisted thoracoscopic surgery (VATS) for thoracic malignancy

Interventions
Two wards were randomized using a random digit table: Ward 1 was allocated to the experimental group and Ward 2 to the control group. Cluster randomisation was performed before participant enrolment.

Experimental group:
Multifunctional rehabilitation belt (bilateral assistive straps, transverse grip bands, detachable grip rings, and adjustable connecting mechanism) for postoperative position shifting and upper-extremity isometric resistance training.

Control group:
Conventional gauze assistive belt (155 cm standard gauze traction band) fixed to bed rails for passive patient repositioning assistance.

The intervention was delivered from postoperative day 1 until hospital discharge (typically 3–7 days post-surgery). Each patient received at least three daily sessions of position training combined with grip strength exercises.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Multifunctional rehabilitation belt

Primary outcome(s)
1. Postoperative time to get out of bed (minutes) measured using using a stopwatch from initiating self-support to stable standing with both feet on the floor at postoperative days 1-3 (first 10 mobilization attempts recorded)

2. Chest drainage tube extubation time measured using days from surgery completion to tube removal at postoperative period until discharge

3. Comfort score during repositioning measured using a 0-10 Numerical Rating Scale at each position change session on postoperative days 1-3

4. Device-related adverse events measured using structured daily monitoring checklist at throughout intervention period

Key secondary outcome(s)

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged 18-75 years
2. Elective VATS for confirmed thoracic malignancy
3. At least one thoracic drainage tube retained postoperatively
4. Intact language and cognitive function
5. Stable vital signs and voluntary participation with signed informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Myasthenia gravis, severe arthritis, or other disorders impairing upper-limb gripping
2. Severe cardiopulmonary, hepatic, renal, coagulation, or autoimmune comorbidities
3. Postoperative activity restrictions ordered by surgeons
4. Cognitive or communication disorders
5. Known allergies to the belt's raw materials

Date of first enrolment
01/06/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
Chongqing University Cancer Hospital

Funder(s)

Funder type

Funder Name
Chongqing University Cancer Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available