

Construction and cost-benefit analysis of a nurse-led management model for chronic wounds in vascular surgery based on the concept of integrated care

Submission date 02/06/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 04/06/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/06/2026	Condition category Circulatory System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific, Public, Principal investigator

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Study information

Scientific Title

Construction and cost-benefit analysis of a nurse-led nursing management model for chronic wound care in vascular surgery

Study objectives

To establish a nurse-led chronic wound management model for vascular surgery under the concept of integrated care, and to evaluate its impact on wound healing, medical costs, and cost-effectiveness ratio.

Ethics approval required

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Ethics approval(s)

Approved 03/02/2026, Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences (No. 99, Longcheng Street, Taiyuan City, Taiyuan, 030032, China; +86 351-8379146; dyyllwyh@163.com), ref: YXLL-2026-036

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Supportive care

Study type(s)

Health condition(s) or problem(s) studied

Nursing care for patients with chronic wounds in vascular surgery

Interventions

Control Group: Conventional Management Model

The traditional diagnosis and treatment model was adopted. Responsible nurses performed dressing changes, condition observation, and basic health education. After discharge, simple telephone follow-up was implemented once a week for 4 weeks, inquiring about wound healing (e.g., exudation, pain), medication compliance, and abnormalities, providing oral guidance. Nursing behaviors were mainly based on executing medical orders, lacking systematic assessment and full-course intervention.

Observation Group: Nurse-led Full-Process Management under Integrated Care Concept

Based on the integrated care theory, a full-process management system was constructed, including wound specialist nurses as leaders, multidisciplinary team collaboration, continuous connection within and outside the hospital, and individualized precise intervention.

Randomization process: A statistician not involved in clinical assessment and intervention independently generated the random sequence using SPSS 26.0. The random numbers were assigned according to enrolment order. Allocation concealment was ensured by sealed, opaque, sequentially numbered envelopes, opened only after baseline assessment. Both groups were treated in the same ward, but interventions were performed by different nursing teams to avoid cross-contamination. All outcome assessors were blinded to group allocation and the intervention process.

Intervention Type

Other

Primary outcome(s)

1. Time to complete wound healing defined as full epithelialisation without exudate, infection, or need for dressing changes measured using Clinical wound assessment against predefined healing criteria at From first intervention to full epithelialisation
2. Pain intensity measured using Visual Analogue Scale (VAS) at admission, discharge, and wound healing or study endpoint
3. Wound infection occurrence measured using clinical diagnosis/medical record review at enrolment to wound healing
4. Wound recurrence rate measured using outpatient or video follow-up assessment at 6 months
5. Patient satisfaction with nursing service measured using self-developed nursing service evaluation scale with 10 items rated on a 5-point Likert scale at discharge or after wound healing
6. Health economic outcomes including cost of care measured using patient records at admission to complete wound healing

Key secondary outcome(s)

Completion date

30/01/2026

Eligibility

Key inclusion criteria

1. Meeting the diagnostic criteria for chronic wounds, referring to the "Expert Consensus on Chronic Wound Care" issued by the Wound Ostomy Nursing Professional Committee of the Chinese Nursing Association, defining a chronic wound as a wound that has not healed within 4 weeks of standardized treatment or shows no tendency to heal
2. Age ≥ 18 years
3. Clear consciousness with basic communication and cooperation abilities
4. Voluntarily participating and signing informed consent

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Male

Total final enrolment

363

Key exclusion criteria

1. Severe functional failure of important organs (cardiac function grade IV, Child-Pugh liver function grade C, chronic kidney disease stage 5 requiring regular dialysis)
2. Malignant tumors, coagulation dysfunction, systemic infectious diseases
3. Cognitive impairment, mental illness, or inability to complete follow-up
4. Missing clinical data or withdrawal midway

Date of first enrolment

02/01/2024

Date of final enrolment

05/12/2025

Locations

Countries of recruitment

China

Sponsor information

Organisation

Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences, Third Hospital of Shanxi Medical University, Tongji Shanxi Hospital

Funder(s)

Funder type

Funder Name

Application Research of Time-point Matching Management Path Based on Pain Trajectory in ASO Patients.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available