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Research on the application of continuous nursing in postoperative rehabilitation of patients with lower extremity varicose veins

Submission date
24/10/2024

Recruitment status
No longer recruiting

Registration date
13/11/2024

Overall study status
Completed

Last Edited
12/11/2024

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate the effectiveness of a continuous nursing model in the postoperative rehabilitation of patients with lower extremity varicose veins.

Who can participate?
Patients diagnosed with lower extremity varicose veins who are undergoing surgical treatment, aged between 18 and 75 years old

What does the study involve?
A control group will receive standard postoperative care, and an experimental group will receive a continuous nursing intervention. The control group's care includes routine wound care, standard discharge instructions, and follow-up appointments as per hospital protocol.

What are the possible benefits and risks of participating?
Implementing a continuous nursing model may enhance the postoperative rehabilitation and overall well-being of patients with lower extremity varicose veins.
No risk factors.

Where is the study run from?
Vascular Surgery, Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences

When is the study starting and how long is it expected to run for?
January 2023 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Junxia Du, dujunxia2024djx@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Research on the application of continuous nursing model in postoperative rehabilitation of patients with lower extremity varicose veins

Study objectives
Implementing a continuous nursing model may significantly enhance the postoperative rehabilitation and overall well-being of patients with lower extremity varicose veins.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 10/04/2024, Ethics Committee of Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences (No. 99 Longcheng Street, Longcheng Street, Xiaodian District, Taiyuan, 030032, China; 8603518379145; dyyllwyh@163.com), ref: YXLL-2024-076

Study design
Single-center interventional double-blind randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Medical and other records, Telephone

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Lower extremity varicose veins

Interventions
A total of 120 patients meeting the inclusion criteria were recruited for the study. Sample size calculation was based on previous studies, assuming a medium effect size with a power of 0.80 and a significance level of 0.05. Participants were randomly assigned to either the control group (n=60) or the experimental group (n=60) using a computer-generated randomization sequence. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes.

The control group received standard postoperative care, and the experimental group received a continuous nursing intervention. The control group's care included routine wound care, standard discharge instructions, and follow-up appointments as per hospital protocol. The experimental group received a comprehensive intervention comprising five key components:
1. Pre-discharge education covering recovery information, wound care techniques, and activity guidelines
2. A home-based care plan featuring personalized exercise regimens, dietary recommendations, and compression therapy guidance
3. Scheduled follow-ups including weekly telephone consultations and bi-weekly home visits for the first month, followed by monthly visits for two months, plus 24/7 hotline access
4. Psychological support with regular mental health assessments and provision of coping strategies
5. Lifestyle modification guidance for long-term recurrence prevention and occupational adaptations, if necessary

Intervention Type
Mixed

Primary outcome measure
1. Wound healing time (in days) measured using data recorded in patient medical notes after surgery
2. Lower extremity function was measured using the Lower Extremity Functional Scale (LEFS) scores at 1, 3, and 6 months post-surgery
3. Pain was measured using the Visual Analog Scale (VAS) at 1 month post-surgery
4. Walking distance (in meters) measured using the standardized 6-minute walk test (6MWT) conducted in a 30-meter indoor corridor at 1-month post-surgery. Patients walked at their self-selected pace for 6 minutes with the total distance recorded.
5. Quality of life measured using the Short Form-36 (SF-36) questionnaire scores at 6 months post-surgery

Secondary outcome measures
1. Psychological status, measured using Beck Depression Inventory (BDI) scoring and Self-Rating Anxiety Scale (SAS) scoring at 6 months post-surgery
2. Activities of daily living measured using Activities of Daily Living (ADL) at 1, 3, and 6 months post-surgery

Overall study start date
06/01/2023

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients diagnosed with lower extremity varicose veins who are undergoing surgical treatment
2. Aged between 18 and 75 years
3. Willing and able to provide informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
120

Total final enrolment

120

Key exclusion criteria
1. Presence of severe comorbidities (such as uncontrolled diabetes or severe cardiovascular disease)
2. Cognitive impairments that could interfere with following postoperative instructions
3. Participation in other clinical trials
4. Pregnancy or breastfeeding

Date of first enrolment
20/01/2023

Date of final enrolment
10/12/2023

Locations

Countries of recruitment
China

Study participating centre
Shanxi Bethune Hospital Shanxi Academy of Medical Sciences
No. 99 Longcheng Street, Longcheng Street, Xiaodian District
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Sponsor information

Organisation
Shanxi Academy of Medical Sciences

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Sponsor type
Hospital/treatment centre

Website
https://m.sxbqeh.com.cn/entry

ROR
https://ror.org/04tshhm50

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The data that support the findings of this study are available from the corresponding author upon reasonable request, Junxia Du, dujunxia2024djx@126.com.

IPD sharing plan summary
Available on request