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Efficacy comparison of Allevyn Gentle Border and conventional dressing in rotator cuff repair

Submission date
30/04/2024

Recruitment status
No longer recruiting

Registration date
01/05/2024

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Wound dressings play an essential role in the healing process by providing a physical barrier between the wound and the external environment, thereby preventing further injury or infection by opportunistic microorganisms from occurring. The optimal wound dressing should be capable of removing multifaceted obstacles in the healing process of skin wounds. Both Allevyn Gentle Border and Cosmopor E Steri1 dressings are applicable for surgical wound management. Although a single sheet of Cosmopor E Steril may seem relatively inexpensive, its limited reusability and frequent need for replacement increase the overall cost of wound management. On the other hand, while a single sheet of Allevyn Gentle Border may seem relatively expensive, its reusability for up to 7 days after removal and waterproof properties are ideal features for patient's self-management of wounds. Therefore, this study will evaluate and compare the non-inferiority of Allevyn Gentle Border compared to Cosmopor E Steri1 in wound management aiming to expand the range of dressing options for managing surgical wounds from rotator cuff repair.

Who can participate?
Patients aged 18 to 80 years old with rotator cuff repair

What does the study involve?
The dressings (Allevyn Gentle Border and Cosmopor E Steri1) will be placed over the surgical wound during the first dressing change post-operation. Every patient will be provided with 3 follow-up visits in the outpatient clinic 1, 2 and 4 weeks after surgery to remove the dressing and evaluate the wound condition.

What are the possible benefits and risks of participating?
Participating patients may reduce dressing change frequency and related costs, enhance postoperative life satisfaction or may not benefit directly from this study. The study will generate essential information, which could be of benefit to others in the future.
Possible adverse events in this study may include but are not limited to peri-wound skin irritation, blistering, redness, stinging or burning while wearing the dressing, pain and itching under the dressing, dressing intolerance, skin damage from medical adhesive and allergic dermatitis. Every possible effort will be taken to minimise the potential of these risks occurring.

Where is the study run from?
West China Hospital, Sichuan University (China)

When is the study starting and how long is it expected to run for?
March 2024 to August 2025

Who is funding the study?
1. National Natural Science Foundation of China
2. Science and Technology Department of Sichuan Province

Who is the main contact?
Prof Peng-cheng Li, hx120120@gmail.com

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Protocol serial number
National Natural Science Foundation of China grant number: 82072514, Science and Technology Department of Sichuan Province grant number: 2022JDKP0091

Study information

Scientific Title
Efficacy of Allevyn Gentle Border dressing versus conventional wound dressing in patients with surgical wounds from rotator cuff repair: a randomized controlled non-inferiority trial

Study objectives
It is hypothesised that Allevyn Gentle Border dressing will be both feasible and acceptable in wound management with rotator cuff repair.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/04/2024, Ethics Committee on Biomedical Research, West China Hospital of Sichuan University (Room 412~413, Laobajiao, No.37 Guoxue Alley, Wuhou District, Chengdu, Sichuan Province, 610041, China; +86 028-65423237; huaxilunli@163.com), ref: 2024 Review (463)

Primary study design
Interventional

Study design
Prospective randomized parallel-controlled single-center open-label trial

Study type(s)
Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
To expand the range of dressing options for managing surgical wounds from rotator cuff repair

Interventions
This is a non-inferiority trial and cost-benefit analysis of silicone adhesive foam dressing for wound management after rotator cuff suture repair. The sample size will be 68 patients who will be randomly assigned 1:1 to an experimental group (34 patients) that will use either the study dressing (Allevyn Gentle Border) or a control dressing (34 patients) of conventional adhesive dressing (Cosmopor E Steri1). The randomization method employed is simple randomization. Specifically, participants will be randomly assigned to the experimental or control group in a 1:1 ratio according to random numbers generated by SPSS version 25.0 (SPSS Inc., Chicago, Illinois, USA). The dressings will be placed during the first dressing change post-operation. Every patient will be provided with 3 follow-up visits in the outpatient at 1 week, 2 weeks, and 4 weeks after surgery, remove the dressing and evaluate the wound condition.

Intervention Type
Device

Phase
Phase 0

Drug/device/biological/vaccine name(s)

Allevyn Gentle Border dressing, Cosmopor E Steri1 dressing

Primary outcome(s)
The following primary outcome measures will be assessed using data collected from study records at 1, 2 and 4 weeks after surgery:
1. Incidence rate of wound complications
2. The cost-effectiveness of wound care, analyzed using the cost-effectiveness ratio (CER) and incremental cost-effectiveness ratio (ICER). The total direct costs related to surgical wound care will include registration fees, dressing change costs, dressing costs and the cost of management of complications

Key secondary outcome(s)
The following secondary outcome measures will be assessed, unless stated, using data collected from study records at 1, 2 and 4 weeks after surgery:
1. Wound healing rate
2. Healing time
3. Dressing wear time
4. Number of dressing changes
5. Clinician's evaluation of dressing performance characteristics measured using a Likert 4-point scoring method
6. Patient's evaluation of the dressing measured using a Likert 4-point scoring method

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Age between 18 and 80 years
2. Undergoing initial rotator cuff repair
3. Surgical procedures will be performed by the same surgeon using the same surgical technique and suture materials
4. Good patient compliance and regular follow-ups are essential
5. Voluntary participation in the study with signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Patients with conditions that may affect wound healing, including hypertension, diabetes, hypoproteinemia, malnutrition (defined as body mass index or BMI < 18.5 kg/m2), severe obesity (defined as BMI > 28 kg/m2), rheumatoid disease, tumor, connective tissue disease, hemophilia, limb vascular disease, psoriasis, radiation injury, gangrene, genetic diseases, anemia, gout, or other diseases that may affect wound healing
2. Long-term use of immunosuppressive agents, glucocorticoids, biological agents, anticoagulants, antiplatelet drugs, or no standardized adjustment and withdrawal pre-surgery
3. Long-term history of smoking or alcohol consumption
4. Preoperative history of surgery or infection at the surgical site
5. Scars, skin lesions, or rashes at the surgical site pre-surgery
6. Recent history (within 1 month) of invasive procedures, such as acupuncture, small needle knife, or drug injection at the surgical site
7. Psoriasis, eczema, dermatitis or other skin diseases
8. Allergic to any dressing components

Date of first enrolment
01/12/2024

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
China

Study participating centre
West China Hospital, Sichuan University
No.37 Guoxue Alley, Wuhou District
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Sponsor information

Organisation
West China Hospital of Sichuan University

ROR
https://ror.org/007mrxy13

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Science and Technology Department of Sichuan Province

Alternative Name(s)
Sichuan Provincial Department of Science and Technology, Department of Science and Technology of Sichuan Province, Science & Technology Department of Sichuan Province, , SPDST

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author, Prof Peng-cheng Li, 16699411@qq.com.

IPD sharing plan summary

Available on request