

Princess Margaret Hospital

Research Information Sheet and Informed Consent Form

You are invited to take part in this research about use of dressing on surgical incision after colorectal surgery. Before you decide to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask us if there is anything that is not clear and/or if you would like more information. Take time to decide whether you wish to take part in this research. If you would like to participate, you need to sign this consent form and keep a copy. You can quit this research in any time, without a reason, but just inform our investigator. You will be updated timely of any information relevant to your willingness to continue participation in the research. This decision will not affect the medical treatment you deserved. During this research, you will not have to pay extra medical expenses or receive any money for it.

1) Research title

- Effectiveness in preventing surgical site infection by using prophylactic occlusive ionic silver-containing dressing in abdominal colorectal surgery patients – randomized controlled trial

2) Research purpose

- Ionic silver-containing dressing has been proven as a broad spectrum antimicrobial agent to reduce inflammation of wounds and promote healing. However, surgical incisions are usually dressed with conventional gauze dressing in abdominal colorectal surgery. Therefore, we are going to carry out a clinical research to compare the effectiveness in preventing surgical site infection by using conventional gauze dressing and occlusive ionic silver-containing dressing
- This is a one year randomized controlled trial and is conducted by the Central Nursing Division and Surgery Department of Princess Margaret Hospital, Hong Kong

3) Research subject

- 200 patients who undergo emergency or elective colorectal surgery will be eligible for enrollment

4) Research procedure

- Enrolled patients with colorectal surgery will be blinded and randomly assigned to have the surgical incisional wound dressed with conventional gauze dressing or occlusive ionic silver-containing dressing
- Researchers will collect the data about your operation details within 30 days of surgery. They will also visit you on the post-operation day 3 for assessment and contact you or your carer by phone to enquire about your wound condition on the post-operation day 15 and 30

(Carer name: _____ [optional])

Contact number of carer: _____ [optional])

- If you have an allergic reaction to ionic silver-containing dressing such as itchiness and redness of skin around the wound, please inform the investigators or health care provider immediately

5) Confidentiality

- All data are for research purpose only and will be kept strictly confidential according to the privacy regulations of Princess Margaret Hospital. All data will be destroyed by shredding after completion of the research

6) Application of research results

- All data will use for academic purpose or modifying hospital policy only

7) Ethical consideration

- This research is approved by Kowloon West Cluster Research Ethics Committee

8) Research consent statement

Title: Effectiveness in preventing surgical site infection by using prophylactic occlusive ionic silver-containing dressing in abdominal colorectal surgery patients – randomized controlled trial

Please ✓ the box below	
1. I confirm that I have read and understood the information sheet dated on ___/___/___ for the above research and have had the opportunity to ask question	
2. I understand that my participation is voluntary and I may withdraw at any time for any reason without explanation, without penalty and without my medical care or legal rights being affected	
3. I understand and authorize that my medical record will be accessed by responsible investigators concerned in this research	
4. I agree to participate in the above research	

Name of Patient

Date

Signature

Name and Rank of Doctor

Date

Signature

9) Contact for enquiry

If you have any questions about the research, please feel free to contact the investigators Mr. Cheung Chi Yeung or Ms. Lee Ho Yan (Mobile phone number: 92234740, 92253762) within office time (Monday – Friday 09:00 – 17:00)