# How effective is ionic silver and chlorhexidine (SiO<sub>2</sub>- Ag+ Chlorex) spray on pain and reepithelialisation rate in donor site wounds for patients undergoing split skin grafting?

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
17/01/2021		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/02/2021 Last Edited	Completed  Condition category	☐ Results		
		[] Individual participant data		
14/09/2021	Surgery	<ul><li>Record updated in last year</li></ul>		

#### Plain English summary of protocol

Background and study aims

A split thickness skin graft (SSG) is a thin layer of shaved skin is taken from one area of the body to another area which has lost skin covering to get the wound healed. Although new treatment approaches for burn patients undergoing SSG treatment have made progress, there is still a need for better methods to enhance wound healing and recovery. KAdermin (SiO<sub>2</sub>- Ag+ Chlorex) spray is a patented medical device that has gained attention due to its renewable nature, good biocompatibility and excellent physical properties that are of importance for wound healing. The aim of this study is to compare the effectiveness of KAdermin spray on pain and reepithelialisation (healing) rate in donor site wounds for patients undergoing SSG as compared to a hydrocolloid dressing, which is the common practice for patients undergoing split skin grafting.

Who can participate?
All patients requiring SSG

What does the study involve?

After skin grafting the participants are randomly allocated to be treated with either SiO<sub>2</sub>- Ag+ Chlorex spray or a conventional dressing (i.e. the hydrocolloid dressing Syncera Elect Hydro). Pain is measured on days 1-7, 10, 15 and 20 after surgery.

What are the possible benefits and risks of participating?

Participation will help the researchers to evaluate the effectiveness of ionic silver and chlorhexidine (SiO<sub>2</sub>- Ag+ Chlorex) spray in the healing of donor site wounds for patients undergoing split skin grafting. The risk of this study is possible adverse effects, such as allergies or infection occurring within the study duration. Affected participants will be discontinued from this study and will be treated accordingly. However, as a step to ensure patient's safety, a patch test will be conducted on patients to identify those allergic to KAdermin spray.

Where is the study run from? Hospital Canselor Tuanku Muhriz, UKM Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for? August 2019 to April 2022

Who is funding the study? Y.S.P Industries (Malaysia)

Who is the main contact? Hani Atiqah Saim hanisaim88@gmail.com

## Contact information

## Type(s)

**Public** 

#### Contact name

Dr Hani Atiqah Saim

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

JEP-2020-727

# Study information

#### Scientific Title

Effect of ionic silver and chlorhexidine (SiO<sub>2</sub>- Ag+ Chlorex) spray on pain and re-epithelialisation rate in donor site wounds for patients undergoing split skin grafting (SSG) - a study protocol

## **Study objectives**

#### Current hypothesis as of 14/09/2021:

There will be improvement in pain and re-epithelialisation rate of skin graft donor sites when treated with SiO<sub>2</sub>- Ag+ Chlorex spray as compared to conventional dressing i.e. hydrocolloid dressing (Syncera Elect Hydro).

#### Previous hypothesis:

There will be improvement in pain, re-epithelialisation rate and scarring of skin graft donor sites when treated with  $SiO_2$ - Ag+ Chlorex spray as compared to conventional dressing i.e. Duoderm.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 16/12/2020, Research Ethics Committee Universiti Kebangsaan Malaysia (Faculty of Medicine UKM, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Wilayah Persekutuan Kuala Lumpur, Malaysia; +60 (0)391455046; sepukm@ukm.edu.my), ref: JEP-2020-727

#### Study design

Prospective pilot randomized controlled trial, concealed allocation, assessor and participants blinded

#### Primary study design

Interventional

#### Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Split skin grafting

#### **Interventions**

Current intervention as of 14/09/2021:

After recruitment and baseline testing, patients will be randomly assigned to the KAdermin and Syncera Elect Hydro groups. A random allocation sequence will be produced using a computer-generated randomisation sequence on Microsoft Excel; patients will be numbered and randomised into two groups. The allocation sequence will be sealed in identical opaque envelopes and given to the enrolling assessor upon receipt of patient consent. Assessor and all participants will be blinded. To ensure that the assessor is blinded, the nurse in charge will remove the dressings, take the donor site photo and send it to the assessor. The assessor will have no contact with the patients.

Intra-operatively, the donor site will be checked and prepared in a sterile fashion, using an antibacterial solution (i.e. povidone iodine) and will be dried. The donor site will then be measured and marked to ensure that the appropriately sized skin graft is harvested. The control group will be dressed using Syncera Elect Hydro, and the intervention group will be dressed with SiO<sub>2</sub>- Ag+ Chlorex spray (KAdermin spray).

#### Previous intervention:

Intra-operatively, the donor site will be checked and prepared in a sterile fashion, using an antibacterial solution (i.e. povidone iodine) and will be dried. The donor site will then be measured and marked to ensure that the appropriately sized skin graft is harvested. The control group will be dressed using Duoderm, and the intervention group will be dressed with SiO<sub>2</sub>- Ag+ Chlorex spray (KAdermin spray). After recruitment and baseline testing, patients will be randomly assigned to the KAdermin and Duoderm groups. A random allocation sequence will be produced using a computer-generated randomisation sequence on Microsoft Excel; patients will be numbered and randomised into two groups. The allocation sequence will be sealed in identical opaque envelopes and given to the enrolling assessor upon receipt of patient consent. Assessor and all participants will be blinded. To ensure that the assessor is blinded, the nurse in charge will remove the dressings, take the donor site photo and send it to the assessor. The assessor will have no contact with the patients.

#### **Intervention Type**

Device

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

Syncera Elect Hydro, SiO<sub>2</sub>- Ag+ Chlorex spray (KAdermin spray)

#### Primary outcome(s)

Pain measured using Visual Analogue Scale (VAS) at rest and dressing removal at baseline, and postoperative days 1-7, 10, 15 and 20

#### Key secondary outcome(s))

Current secondary outcome measures as of 14/09/2021:

- 1. Re-epithelialisation rate of skin graft donor sites will be evaluated on postoperative days 5, 10, 15 and 20. During the wound assessment, standard photography with the same camera, settings and lighting condition will be carried out. The photographs will be assessed; epithelialisation percentage will be calculated by analysing the photographs of the donor sites using image software (Adobe Photoshop®).
- 2. Patient satisfaction will be measured with a questionnaire at Day 15 post SSG

Previous secondary outcome measures:

- 1. Re-epithelialisation rate of skin graft donor sites will be evaluated on postoperative days 5, 10, 15 and 20. During the wound assessment, standard photography with the same camera, settings and lighting condition will be carried out. The photographs will be assessed; epithelialisation percentage will be calculated by analysing the photographs of the donor sites using image software (Adobe Photoshop®).
- 2. Scarring will be assessed with the Vancouver Scar Scale (VSS) and Patient and Observer Scar Assessment Scale (POSAS) at Day 15, 20 and 45 post SSG
- 3. Patient satisfaction will be measured with a questionnaire at Day 15 post SSG

#### Completion date

# **Eligibility**

## Key inclusion criteria

- 1. All patients undergoing split skin grafting using the thigh as a donor site
- 2. Consented patients

## Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

All

#### Sex

All

#### Key exclusion criteria

- 1. Known allergy to any component of the dressings
- 2. Uncontrolled diabetes mellitus, as measured by HbA1c ≥10%
- 3. Presence of active autoimmune or immune diseases
- 4. Use of systemic steroid or immunosuppressants

#### Date of first enrolment

11/02/2021

#### Date of final enrolment

09/04/2022

## Locations

#### Countries of recruitment

Malaysia

## Study participating centre

Pusat Perubatan Universiti Kebangsaan Malaysia

Jalan Yaacob Latif Bandar Tun Razak Malaysia 56000

# Sponsor information

## Organisation

University Kebangsaan Malaysia Medical Centre

#### **ROR**

https://ror.org/01590nj79

# Funder(s)

## Funder type

Industry

#### **Funder Name**

Y.S.P Industries

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The data will be available with the publication of the final manuscript as a supplemental document.

## IPD sharing plan summary

Other

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes