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How effective is ionic silver and chlorhexidine (SiO_2- Ag+ Chlorex) spray on pain and re-epithelialisation rate in donor site wounds for patients undergoing split skin grafting?

Submission date
17/01/2021

Recruitment status
No longer recruiting

Registration date
08/02/2021

Overall study status
Completed

Last Edited
14/09/2021

Condition category
Surgery

[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
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_2- 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 re-epithelialisation (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_2- 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_2- 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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
JEP-2020-727

Study information

Scientific Title
Effect of ionic silver and chlorhexidine (SiO_2- 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_2- Ag+ Chlorex spray as compared to conventional dressing i.e. hydrocolloid dressing (Syncera Elect Hydro).

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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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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_2- Ag+ Chlorex spray (KAdermin spray).

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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_2- 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_2- Ag+ Chlorex spray (KAdermin spray)

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

Secondary outcome measures
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

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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

Overall study start date
03/08/2019

Completion date
09/04/2022

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

Age group
All

Sex
Both

Target number of participants
12 patients for each arm. Total 24 patients.

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
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Sponsor information

Organisation
University Kebangsaan Malaysia Medical Centre

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/01590nj79

Funder(s)

Funder type
Industry

Funder Name
Y.S.P Industries

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The protocol will be available at a later date.

Intention to publish date
09/04/2023

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