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Effects of polyphenols extracted from Moringa oleifera leaves to heal split-thickness skin graft donor site wounds

Submission date
28/04/2024

Recruitment status
No longer recruiting

Registration date
07/05/2024

Overall study status
Completed

Last Edited
07/05/2024

Condition category
Skin and Connective Tissue Diseases

[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
Split skin grafting is a surgical procedure used worldwide in which the surgeon harvest split skin from a healthy part of the body to cover and speed the healing of a large wound from the same patient. In low-income settings this large wound faces challenges to heal within a reasonable time causing more patient morbidity, additional cost and lack of productivity. The new wound caused by the surgeon is the donor site wound which is usually painful, takes 2 weeks or more to completely heal and is exposed to the risk of infection. Currently there is lack of standardization regarding the best primary dressing material to use for donor-site wound healing.
Many studies have demonstrated that extracts from Moringa oleifera leaves have wound-healing potential and can be used to reduce time to wound healing, pain and rate of infection. This study aims to compare paraffin gauze impregnated with extracts from Moringa oleifera leaves to the standard non-impregnated paraffin gauze as a wound dressing material for split skin graft donor sites.

Who can participate?
Patients aged 5 to 45 years old with a large wound requiring a split-thickness skin graft

What does the study involve?
Participants will undergo split skin graft surgery and will be randomly allocated either to the experimental group (dressing with Moringa oleifera extracts) or the control group (dressing with none impregnated paraffin gauze). At least 1 month follow-up is required.

What are the possible benefits and risks of participating?
Participants will benefit from scar follow-up and management free of charge for 1 year. No adverse effects and no toxicity have been reported with Moringa oleifera leaf extracts so far and the plant is widely used in cosmetics and nutrition. However, the researchers cannot guarantee the complete absence of side effects to participants. In case this happens management of side effects will be free of charge.

Where is the study run from?
Provincial Hospital of North Kivu (Democratic Republic of the Congo)

When is the study starting and how long is it expected to run for?
June 2021 to March 2025

Who is funding the study?
1. Investigator initiated and funded
2. Ambassade de France à Kinshasa (Democratic Republic of the Congo)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
WH001MO

Study information

Scientific Title
Effectiveness of polyphenols extracted from Moringa oleifera leaves in split-thickness skin graft donor site wound healing: a double-blind randomized control trial

Acronym
PoMoDoWH

Study objectives
Primary dressing of split-thickness skin graft donor site wound with polyphenols extracted from Moringa oleifera leaves grown in South Kivu improves donor site healing.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/01/2022, Comité d'éthique médicale (University of Goma, Avenue Eugene Serufuli No 43, Goma, 204, Congo, Democratic Republic; +243 (0)999257903; comite.ethique@unigom.ac.cd), ref: UNIGOM/CEM/001/2022

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Split-thickness skin graft donor site wound

Interventions
The researchers will conduct a double-blind clinical trial during which neither the assessor of completeness of donor site wound epithelialization nor the patient will be informed of the nature of the primary dressing used.

After getting the patient's consent for the study and the operation the patient will be randomly allocated to the control or experimental group. Using the online ResearchRanzomizer application 122 numbers (from 1 to 122) were randomly distributed into two groups comprising 61 numbers each, group 1 (control) and group 2 (experimental).

Group 1: 79,11, 26, 88, 92, 25, 12, 104, 32, 118, 47, 29, 18, 109, 28, 101, 87, 111, 115, 78,66, 37,83, 52, 40, 72, 1, 34, 14, 77, 21, 6, 58, 108, 50, 75, 56, 19, 84, 113, 97,96, 67, 45, 85, 16, 99, 93, 8, 31, 3, 120, 107,43, 54, 10, 53,65, 42, 2, 81.
Group 2 : 4, 17, 7, 22, 27, 39, 30, 5, 105, 116, 41, 48, 63, 36, 15, 76, 38, 62, 102, 46, 49, 60, 117, 44, 86, 82, 59, 70, 61, 24, 64, 89, 122, 55, 90, 20, 100, 112, 119, 121, 57, 114, 13, 51, 103, 98, 106, 68, 23, 71, 73, 95,35, 94, 9, 80, 91, 110, 33, 69, 74.

For each new patient meeting the study selection criteria, a draw will be made by a nurse from a box containing 122 numbers (from 1 to 122) written on small pieces of paper folded to hide the number and mixed in the box. The number drawn will be found in the pre-established group (see allocation sequence above) in order to define the type of primary dressing that will be administered. The number drawn will be excluded from the box and will not participate in future draws.

The induction of anesthesia will be preceded by antibiotic prophylaxis with ampicillin 2 g in adults and 100 mg/kg in children by slow direct intravenous injection (single dose) and the operating checklist. Disinfection of the donor site will precede that of the recipient site and will be done with Betadine 10%.
A skin grafting knife (Wilson's brand) will be used to harvest 0.4 mm of split-thickness skin after applying a sterile lubricating gel to the skin. Hemostasis by application of gauzes soaked in adrenaline diluted 1:100,000 will be achieved. The harvested skin will be temporarily stored in a sterile kidney dish containing 0.9% normal saline until the completion of skin harvest. They will be hand-meshed with a scalpel before their fixation to the recipient site. A different team will fix the graft after reviving the recipient site wound bed. The sizes of the donor site wound will be measured using a sterile ruler and noted on the patient's form.

Each dressing change will be performed in accordance with the principles of infection prevention and control (IPC). In the control group the primary dressing of the donor site will be done with sterile paraffin gauze while for the patients in the experimental group paraffin gauze will be impregnated with total polyphenol powder, extracted from Moringa oleifera leaves, concentrated at 20%.

The secondary dressing material in both groups comprises a layer of dry cotton pads then a Velpeau crepe bandage secured with adhesive tape.
For postoperative analgesia intramuscular pethidine at a rate of 1 mg/kg every 4 hours for the first 2 postoperative days will be administered; oral paracetamol at a rate of 15 g/kg every 8 hours will be administered from the first to the fifth postoperative day.

On each donor site dressing change scheduled on Days 7, 10, 13, 16, 20, 24 and 28 the rate of donor site wound epithelialization will be assessed using a sterile transparent plastic measuring guide from the Medline brand and the Bates-Jensen Wound Assessment Tool (BWAT) will be completed. Photos of the donor site wound will be taken at each dressing change using a Nikon D 3100 brand camera. The first recipient site dressing change will be done on day 5 or earlier if there is a sign of infection. Wound-related pain will be assessed using the combined numeric visual analogue scale (VAS) and the Wong-Baker Scale before and 6 hours after each dressing change in both groups.

Neither the assessor of completeness of donor site wound epithelialization nor the patient will be informed of the nature of the primary dressing used. This latter will be covered by a layer of cotton pad and a Velpeau crepe bandage.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Polyphenols extracted from Moringa oleifera leave

Primary outcome(s)
Time to complete wound epithelialization assessed using a sterile transparent plastic measuring guide from the Medline brand and the Bates-Jensen Wound Assessment Tool (BWAT) on Days 7, 10, 13, 16, 20, 24 and 28

Key secondary outcome(s))
1. Wound-related background pain measured using visual analogue scale (VAS) and the Wong-Baker Scale on days 7, 10, 13, 16, 20, 24 and 28
2. Rate of wound infection measured using culture and sensitivity of wound swab whenever clinical sign of infection is suspected
3. Quality of scar measured using the Patient and Observer Scar Assessment Scale (POSAS) at day 28
4. The economic value of the dressing material measured using the Incremental Cost-Effectiveness Ratio (ICER) at complete wound epithelialization

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Aged 5 to 45 years old
2. Requiring split-thickness skin graft
3. Clinically stable
4. Consented to the study
5. Extent of the donor site wound is less than 10% of the body surface area

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
5 years

Upper age limit
45 years

Sex
All

Key exclusion criteria
1. Mental illness
2. Patients staying less than 6 months in the city
3. History of hypersensitivity reaction to Moringa oleifera derivatives
4. Immunodeficiency state
5. Pregnancy
6. Age below 5 years or over 45 years
7. Patient suffering from condition that may interfere with wound healing: diabetes, renal or hepatic insufficiency, malignant tumor, hypoalbuminemia (serum albumin <4 g/dL), malnutrition, smoking

8. Does not wish to participate in the study
9. Clinical condition deteriorates during the study
10. Decided to stop participating in the study
11. Discontinuation of treatment
12. Death during the study

Date of first enrolment
26/05/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Congo, Democratic Republic

Study participating centre
Hopital Provincial du Nord Kivu
Route Saké, Commune de Goma
Goma
Congo, Democratic Republic
576GOMA

Sponsor information

Organisation
Université de Goma

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Ambassade de France à Kinshasa

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary

Not expected to be made available

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