ISRCTN17883369 https://doi.org/10.1186/ISRCTN17883369

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

Submission date
28/04/2024

Recruitment status
Recruiting

Registration date
07/05/2024

Overall study status
Ongoing

Last Edited
01/04/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 18 to 45 years old with a 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?
November 2025 to December 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Tshimbila Kabangu, jmtkab@unigom.ac.cd, jmtkab@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Tshimbila Kabangu

ORCID ID
https://orcid.org/0000-0002-4781-7996

Contact details
Avenue Bougainvillier No 145
Quartier Les Volcans
Commune de Goma
Goma
Congo, Democratic Republic
204
+243 (0)976764798
jmtkab@unigom.ac.cd

Additional identifiers

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
Current study objectives as of 01/04/2026:

General objective:
To evaluate the effect of paraffin gauze impregnated with a polyphenolic extract from Moringa oleifera leaves on complete re-epithelialization and pain at the donor site of split-thickness skin grafts.

Specific objectives:
1. To compare the mean time (days) to complete re-epithelialization between polyphenolic extract–impregnated paraffin gauze, total extracts (aqueous and methanolic), and non-impregnated paraffin gauze;
2. To assess the analgesic effect of polyphenolic extract–impregnated paraffin gauze compared with total extracts and control.

_____

Previous 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)
Efficacy, Prevention, Quality of life, Treatment

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

Interventions
Current interventions as of 01/04/2026:

Perioperative asepsis and sterility of instruments will be ensured. Participants will receive antibiotic prophylaxis with ampicillin 2 g IV one hour before anesthesia. Under spinal anesthesia, a 0.25 mm split-thickness skin graft will be harvested from the donor site using a manual dermatome after povidone-iodine disinfection and sterile draping. Hemostasis will be achieved using gauze soaked in adrenaline diluted 1:100,000. The harvested graft will be immediately placed in sterile normal saline.

Participants will be randomized into experimental or control groups. At the donor site, the experimental group will receive paraffin gauze impregnated with either the polyphenolic extract

or the total extracts (aqueous and methanolic) of Moringa oleifera leaves. The control group will receive non-impregnated paraffin gauze. In both groups, a secondary occlusive absorbent dressing will be applied. The extract is applied to the surface of the gauze in contact with the wound bed.
At the recipient site, the graft will be fixed with 4/0 Vicryl after wound bed preparation and hemostasis. A primary dressing of non-impregnated paraffin gauze, followed by a secondary occlusive absorbent dressing, will be applied. No postoperative antibiotics will be administered. All participants will receive standardized analgesia: tramadol 100 mg every 8 hours plus paracetamol 1 g administered 4 hours after tramadol during the first three postoperative days. Pain (Visual Analogue Scale, at rest and on movement) and donor site healing (time to complete re-epithelialization) will be assessed on days 3, 5, 7, 10, 14, 17, 21, and 28. Donor site dressings will be changed at each assessment after cleaning with sterile saline, and wound measurements and photographs will be recorded.

_____

Previous 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)
Polyphenolic and total extracted from Moringa oleifera leave

Primary outcome(s)
Current primary outcome(s) as of 01/04/2026:

Mean 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

———

Previous 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))
Current key secondary outcome(s) as of 01/04/2026:

1. Wound-related background pain measured using visual analogue scale (VAS) and the Wong-Baker Scale on days 3, 5, 7, 10, 14, 17, 21, and 28.
2. Rate of wound infection measured using culture and sensitivity of wound swab whenever clinical sign of infection is suspected

---

Previous 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
30/12/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 01/04/2026:

1. Aged 18 to 45 years
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
6. Ability to be followed up until postoperative day 28

Previous 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

Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 01/04/2026:

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 18 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

———

Previous 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
03/11/2025

Date of final enrolment
30/11/2026

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available