ISRCTN12417689 https://doi.org/10.1186/ISRCTN12417689

Does compression therapy reduces the time it takes for wounds to heal after surgical removal of a keratinocyte skin cancer on the lower leg?

Submission date
05/12/2023

Recruitment status
No longer recruiting

Registration date
21/12/2023

Overall study status
Ongoing

Last Edited
08/09/2026

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Skin cancers are common and the number of people who are developing them is increasing. They are usually split into two groups: melanomas are less common but more serious and keratinocyte skin cancers are more common but less serious. Keratinocyte skin cancers can occur anywhere in the body. Most need to be cut out. Keratinocyte skin cancers that develop on the leg often cannot be closed with stitches and the wounds are left to heal by themselves (known as secondary intention wound healing). When left open, they can take several months to heal and can occasionally develop complications such as infections. This project is trying to find out if compression therapy reduces the time it takes for wounds to heal by themselves after surgical removal of a keratinocyte skin cancer on the lower leg.

Who can participate?
All adult patients aged 18 years old and over attending a Skin Cancer Surgical Centre (SCSC) who have a keratinocyte skin cancer on the lower leg which is planned to be surgically removed and left to heal by secondary intention.

What does the study involve?
The study will involve 396 patients from approximately 20 hospitals, who have had surgical removal of a keratinocyte skin cancer and have a wound which is allowed to heal by itself. Patients will have a 1 in 2 (50%) chance of receiving standard care or standard care with compression therapy.

What are the possible benefits and risks of participating?
Participants will benefit from being closely monitored by the research team in addition to the care they will receive as part of local practice. Those receiving compression may find some benefits to compression therapy, such as relief from aching legs provided by the additional support.

Minimal risk is anticipated for participants as the safety profile of compression therapy is well known and is in routine use across the NHS. The following risks have been identified and steps to

minimise;
1. Discomfort
Participants will be advised to take paracetamol or other painkillers as prescribed (as per standard practice). It is expected that the discomfort will lessen as the wound begins to heal, however, participants may change to a different type of compression therapy, or stop using compression therapy if they are finding it too painful and will remain in the study.
2. Skin Irritation
Compression therapy can cause skin dryness or rubbing and mild irritation. Participants can use creams/ointments as directed by their healthcare team and change to a different type of compression or stop using compression therapy and remain in the study.

Where is the study run from?
The trial is centrally coordinated by the Leeds Clinical Trials Research Unit (CTRU) based at the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
July 2023 to February 2027.

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
HEALS2@leeds.ac.uk (UK)

Contact information

Type(s)
Public, Scientific

Contact name
Dr HEALS2 Trial Team

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Additional identifiers

Integrated Research Application System (IRAS)
332091

Central Portfolio Management System (CPMS)
58011

Study information

Scientific Title
Secondary intention wound healing following excision of keratinocyte cancers on the lower leg (HEALS2)

Acronym
HEALS2

Study objectives
Current study objectives as of 29/06/2026:

Primary objective:
The primary objective is to compare the time to healing by secondary intention from randomisation, between SC or SC plus CT.

Secondary objectives:
Secondary objectives will compare groups for:
1. Incidence of infection as measured by modified Bluebelle Wound Healing Questionnaire (WHQ) (20) until healing
2. Numbers of days participants prescribed antibiotics until healing
3. Scar quality as measured by Patient and Observer Scar Assessment Scale (POSAS)(21)
4. Safety events including related complications and hospitalisations until healing (maximum 52 weeks post randomisation)
5. Cost effectiveness via a within-trial and decision analytic model assessed from a payer perspective measuring patient health related quality of life in terms of Quality Adjusted Life Years (QALYS) meeting updated Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 updated reporting guidance(22)
6. Resource use and Health-related quality of life (HRQoL) as measured by EuroQol 5 Dimensions 5 Levels questionnaire (EQ-5D-5L) to 26 weeks post randomisation (52 weeks where applicable, for unhealed participants only).
7. The relationship between post-partial closure wound area, type of partial closure method, and time to healing

Exploratory objectives:
1. Explore associations between short-term wound area reduction between baseline and 4 weeks post randomisation and time to healing by secondary intention
2. Explore patient acceptability and factors affecting adherence to randomised treatment
3. Associations will be explored between wound breakdown post healing and the use of compression therapy

Qualitative sub study objectives:
1. Challenges and difficulties encountered during CT
2. Impact CT has on daily activities and quality of life
3. Patients' satisfaction with the support provided
4. Factors influencing patients' decisions to continue or discontinue CT

Previous study objectives:

To compare the time to healing from randomisation, between standard care or standard care plus compression therapy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/11/2023, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8012; leedseast.rec@hra.nhs.uk), ref: 23/YH/0247

Primary study design
Interventional

Study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer and neoplasms

Interventions
Screening
Adults who have been referred for removal of skin cancer on the lower leg and the surgeon has decided that they will not be able to fully close the wound will be screened by the clinical team. The clinical pathway before surgery varies between hospitals, with some hospitals using 'teledermatology' via phone calls or video calls and some hospitals seeing patients in person.
At sites using teledermatology, the study will be discussed with the clinical team during the pre-operative telephone or video call. Assenting patients will receive full study information by email /post/online link and a follow-up appointment to provide consent made with a member of the research team at a time convenient for the patient.
Where patients attend pre-operative in-person visits as part of the clinical pathway, an invitation letter will be provided with their clinic letter OR the study will be discussed at this appointment. Assenting patients will be provided with full information about the study by email/post/online link and a follow-up appointment to provide consent made with a member of the research team at a time convenient to the patient.
At sites where the pre-operative consultation takes place on the same day as surgery, patients will be screened by the attending clinical team and where indicated, will be provided with study information at their appointment by the clinical or research team to consider at the visit. Assenting patients can complete consent at that visit before surgery. Alternatively, a short study information leaflet can also be included with the appointment letter with contact details for the local research team. Patients may then contact the research team to discuss the study, their eligibility and the consent process.
Consent Patients will have as long as they need to consider participation, and consent may be taken on the same day as randomisation if the patient is happy to do so.
Consent can be taken via one of the methods below:
(i) Remote eConsent
The participant will receive a link to the eConsent system before the remote eConsent phone /video call. During the call, the patient will complete all questions, add a signature (by clicking a

button) and submit the form. The participant will receive an electronic copy of the completed form, or the researcher may print and post a copy if requested. The eConsent system is hosted by the CTRU, it is password protected. A copy of the eConsent can be seen by CTRU staff but the CTRU does not save a printed/downloaded copy. Sites can access a copy for their records.
(ii) Remote verbal consent
For participants unable to complete remote e-consent (e.g. electronic device accessibility), the researcher will read each statement on the consent form to the patient, initialling and signing the paper consent form on behalf of the patient. A copy of the consent form signed on behalf of the patient will then be posted/emailed to the patient.
(iii) In person
This can be done using a paper copy of the consent form, or via eConsent (on a tablet/electronic device, depending upon availability) Following consent, the participant will be asked to complete a questionnaire (EQ-5D-5L) and baseline assessments will be completed, these will include demographic information, medical history, assessment of arterial supply to lower limb (Ankle Brachial Pressure Index or toe pressure).
Surgery will take place as planned and randomisation will take place following confirmation of the wound measurement.
Post-surgery
The participant will receive their allocated treatment and information as required.
Follow-up - Participants will receive phone calls until their wound has healed. Phone calls will be weekly up to a maximum of 6 months. If the wound remains unhealed after 6 months, patients may continue to receive monthly phone calls until the wound has healed up to a maximum of 12 months. - The participant will be asked to complete questionnaires after 12 weeks and 26 weeks (and 52 weeks if not healed). These will be sent to the patient via their preferred method (electronic, postal, or telephone administration).
- After 4 weeks participants will be asked to attend an in-person visit where the wound will be assessed, and a photograph taken, and the participant will be asked to complete some questionnaires (there will be no phone call this week).
- If the participant reports that their wound has healed, they will be invited to attend an in-person visit to confirm healing. The wound will be assessed, a photograph taken, the participant and healthcare professional will be asked to complete a questionnaire to assess the quality of their scar.
Patient interviews
Participants in the intervention arm who agree to be approached on the main consent form may be contacted by phone to explore the acceptability of the intervention. This will be investigated using qualitative methods, with a detailed separate protocol which will be submitted for separate ethics and HRA approval.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The time to complete healing (epithelialisation) of the surgical wound from randomisation to the date the wound is confirmed as healed measured using clinical assessment of the wound at a clinical assessment visit scheduled within 7 days of a verbal report of healing

Key secondary outcome(s)
1. Incidence of infection measured using the modified Bluebelle Wound Healing Questionnaire (WHQ) until healing at 4, 12, 26 and 52** weeks
2. Number of days participants were prescribed antibiotics until healing measured using participant responses during follow-up telephone calls collected weekly to 26 weeks, monthly

from 26 to 52 weeks
3. Scar quality measured using the Patient and Observer Scar Assessment Scale (POSAS) at the confirmation of the healing visit
4. Safety events including related complications and hospitalisations until healing measured using participant responses during follow-up telephone calls weekly to 26 weeks, monthly from 26 to 52 weeks
5. Health-related quality of life measured using the EQ-5D-5L at baseline, 4, 12, 26, 52*** weeks
6. The relationship between post-partial wound closure area, type of partial closure method, and time to healing measured using wound area measurement calculated from maximum length and width taken during surgery, post partial closure

Key
**only conducted if not healed at 6 months
***Unhealed participants only

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Aged > = 18 years
2. Planned excision of suspected KC on the lower leg with healing by secondary intention
3. Ankle-brachial pressure index (ABPI) > = 0.8 or toe pressure of > 60 mmHg
4. Informed written/eConsent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Planned primary closure/skin graft/flap
2. Receiving/planned compression for another indication

3. Severe venous incompetence e.g. Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification C5 or C6
4. Contraindication to at least medium compression(18-24mmHg)
5. Unable to comply with compression
6. Suspected to have a non-KC diagnosis or require further surgery
7. Previously taken part in HEALS2

Date of first enrolment
15/02/2024

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Manor Hospital
Moat Road
Walsall
England
WS2 9PS

Study participating centre
Aneurin Bevan University Lhb
Headquarters - St Cadoc's Hospital
Lodge Road
Caerleon
Newport
Wales
NP18 3XQ

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Warwick Hospital
Lakin Road
Warwick
England
CV34 5BW

Study participating centre
Royal Liverpool University Hospital NHS Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
England
L7 8XP

Study participating centre
Walsall Healthcare NHS Trust
Manor Hospital
Moat Road
Walsall
England
WS2 9PS

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generate datasets to be involved in subsequent uses of those datasets.

Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree on suitable requirements for release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/09/2026	08/09/2026	Yes	No
Participant information sheet	version 2.0	21/11/2023	18/12/2023	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes