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A prospective study using the KerraCel™ dressing on multiple wound types

Submission date
15/09/2021

Recruitment status
No longer recruiting

Registration date
15/11/2021

Overall study status
Completed

Last Edited
24/07/2025

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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
The KerraCel™ dressing is a CE-marked product that has been on the market since 2013. It contains gelling fibers that can soak up the fluid that can be created by wounds on the skin. The aim of the study is to collect additional information on the dressing to show that it is working as intended.

Who can participate?
Patients aged 22 years or older and being seen for these types of wounds: Oncology wounds, traumatic wounds, cavity wounds, skin donor site. Examples of these can be: Oncology - radiation burns, cancerous wounds or wounds that occur after surgical removal of cancer. Traumatic - abrasions (deep scrapes) or lacerations. Cavity - wounds in a cavity (such as addomen or chest). Donor sites where skin has been removed for grafting.

What does the study involve?
For patients who meet the requirements to participate, you will be seen 4 times in the office /clinic. On the first visit, you will have a picture taken of the wound and the dressing put over the wound. You will come in 2 additional times, approximately 7 days apart from each visit, to have another picture of the wound taken and another dressing placed over the wound. A final visit will occur (again approximately 7 days from the 3rd visit), where the dressing will be removed and another picture is taken. No surveys will be completed for this study and only small amounts of information such as medical history, medication use, and information about your wound will be collected.

What are the possible benefits and risks of participating?
Possible benefits of the study are the wound dressing may help manage your wound healing, additional follow-up by the staff at the hospital since this is a study, use of a dressing not currently in use at the facility.

Possible risks of participating are the same risks that would occur for treating any open wound with a wound dressing: skin irritation, redness, possible infection, delay in wound healing. One possible risks for this type of dressing is some of the gel material could remain in the wound.

Where is the study run from?
Wythenshawe Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2021 to June 2023

Who is funding the study?
KCI® USA, Inc (now a part of 3M) (USA)

Who is the main contact?
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288315

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KERA_CEL-PMCF007, IRAS 288315, CPMS 47700

Study information

Scientific Title
A prospective, observational, Post Market Clinical Follow-up (PMCF) study in patients using 3M™ KerraCel™ Gelling Fiber dressing

Study objectives
Current hypothesis as of 18/03/2022:
The aim of this study is to describe the population and indications of the KerraCel™ Dressing to demonstrate that the product is performing as expected and is safe specifically on the identified wound types, where it has been identified that additional evidence is needed to support the Clinical Evaluation Report (CER).

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Previous hypothesis:
The aim of this study is to describe the population and indications of the KerraCel™ Dressing to demonstrate that the product is performing as expected and is safe specifically on oncological and traumatic wounds, where it has been identified that additional evidence is needed to support the Clinical Evaluation Report (CER).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/04/2021, London-Westminster Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8388; westminster.rec@hra.nhs.uk), ref: 21/PR/0337

Study design
Single center observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Oncological wounds (e.g. radiation burns, cancerous wounds and surgical wounds once the cancerous tissue has been removed), traumatic wounds (e.g. abrasions and lacerations), cavity wounds (such as abdominal or thoracic) and wounds created from skin donor sites

Interventions
Patients will be seen and evaluated by a clinician to determine if their wound is appropriate to be treated with the KerraCel™ dressing. If yes, the clinician will make general observations of the wound and then dress the wound. Pictures will be taken of the wound initially and at each dressing change.

Patients will be seen 4 times in the office/clinic. On the first visit, a picture is taken of the wound and the dressing put over the wound. At 2 additional visits, approximately 7 days apart from each visit, another picture of the wound is taken and another dressing is placed over the wound. A final visit will occur (again approximately 7 days from the 3rd visit), where the dressing will be removed and another picture taken.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
3M™ KerraCel™ Gelling Fiber Dressing

Primary outcome measure
Treatment-related adverse events measured using patient records up to the final visit (~21-28 days)

Secondary outcome measures
Wound healing and wound bed preparation by visual inspection of at baseline, ~day 7, 14, 21-28:
1. Decrease in wound size (volume, area, or depth)
2. Increase in % of wound granulation tissue
3. Wound moisture evaluation defined as wound exudate levels indicated as optimal
4. Decrease in % of nonviable tissue

Overall study start date
23/04/2021

Completion date
21/06/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/03/2022:
1. Subjects who have been diagnosed with an oncological wound (e.g. radiation burns, cancerous wounds, and surgical wounds once the cancerous tissue has been removed), or traumatic wound (e.g. abrasions and lacerations), or cavity wound (wounds in a cavity) or skin donor site
2. Must be able to provide informed consent
3. Only one wound may be treated per subject for the study
4. Aged ≥22 years

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Previous inclusion criteria:
1. Subjects who have been diagnosed with an oncological wound (e.g. radiation burns, cancerous wounds, and surgical wounds once the cancerous issue has been removed) or traumatic (e.g. abrasions and lacerations) wound.
2. Must be able to provide informed consent.
3. Only one wound may be treated per subject for the study.
4. Age ≥22 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
22 Years

Sex
Both

Target number of participants
50

Total final enrolment
48

Key exclusion criteria
Current exclusion criteria as of 18/03/2022:
1. Has a known allergy to the dressing material
2. Has a wound that has uncontrolled heavy bleeding
3. Wound or burn larger than 20 cm in any direction
4. Pregnant or breastfeeding

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Previous exclusion criteria:
1. Has a wound that requires packing of a body cavity with the KerraCel™ dressing, per the manufacturer’s instructions for use.
2. Has a wound that has not achieved hemostasis, per the manufacturer’s instructions for use.
3. Wound or burn larger than 20cm in any direction.
4. Pregnant or breastfeeding.

Date of first enrolment
01/09/2021

Date of final enrolment
09/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital
University of Manchester & Manchester University NHS Foundation Trust
Southmoor Road
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Sponsor information

Organisation
KCI (United States)

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Sponsor type
Industry

Website
https://www.acelity.com/

ROR
https://ror.org/00wc6ay63

Funder(s)

Funder type
Industry

Funder Name
Kinetic Concepts

Alternative Name(s)
Kinetic Concepts, Inc., KCI USA, KCI

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
At this time, there is no plan to publish the data from this study. This data is intended to be post-market data to support the clinical evidence of the product. The final report is planned for 08/12/2022.

Intention to publish date
15/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the researchers' intent not to publish the data in any journal article or for any business purposes. They will post the study results on the ISRCTN registry as required but that will be the extent of the data shared for this study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No