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Clinical registry collecting real-world evidence on wound care treatments (SIDDX)

Submission date	Recruitment status	[_] Prospectively registered
06/06/2024	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/07/2024	Injury, Occupational Diseases, Poisoning	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will collect data on various wound treatments and their related wound-healing processes in real-life settings.

Who can participate?
All adults requiring wound care

What does the study involve?
Continuation of wound treatment as dictated by the treating physician

What are the possible benefits and risks of participating?
It is hoped that these results will help future participants benefit from an improved wound treatment regime and healing times. Possible risks are allergic or autoimmune response to the biological/synthetic grafts used, since we are strictly observing treatments, the treating providers will be strongly requested to observe for such an incident and report AE/SAE. All products observed are mandated to have FDA clearance, as such risk to the patient is minimal.

Where is the study run from?
Siddhey LLC (United States of America)

When is the study starting and how long is it expected to run for?
April 2024 to March 2029

Who is funding the study?
Siddhey LLC (United States of America)

Who is the main contact?
Mr Chinmay Chauhan (MBA, RN-BSN, BSBE), ChinmayC@siddhey.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name
Mr Chinmay Chauhan

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT06328010

Secondary identifying numbers
Pro00070536

Study information

Scientific Title
An observational clinical registry to collect safety and efficacy data on wound care treatments from a variety of treatment settings

Acronym
SIDDX

Study objectives
The study's primary objection is to collate an observational clinical registry to collect treatment outcomes after biological and synthetic amnion grafts. It is hypothesised that wound treatment will reduce healing time by >40%

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2023, Advarra IRB (6100 Merriweather Dr., Suite 600, Columbia, MD 21044, United States of America; +1 877-992-4724; adviser@advarra.com), ref: SIDDXAC02

The study will not challenge the treatment practice of physicians treating wound (+), and will only collect data on treatment which has been agreed upon by the physician and patients.

Study design
Multicenter observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Care home, GP practice, Home, Hospital, Medical and other records, University/medical school /dental school

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

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Improving heal rate in wound care

Interventions
This is a multicenter observational study enrolling deidentified patients that will collect data on the healing rate of wounds and wound care between the standard of care and many advanced therapeutic interventions.

Physicians, APRNs, and PAs treating patients for any type of "wound" care resulting from conditions such as diabetes, vascular insufficiency, dermatological conditions, or from trauma, surgical/post-surgical events, chemotherapy, burns, and degloving will be observed. The two treatment methods observed will be standard of care (SOC) and treatment with biological or synthetic grafts (advanced treatment modality). The timeframe of 12 weeks (1/week 10 treatment = 10 weeks and 2 weeks post closure/end of 10 weeks follow up) at maximum will be observed. This data will be analyzed to determine the rate of healing via the use of advanced treatment modalities. Since the observational study will not dictate therapy, and very few IC/EC this will be as close to real-world evidence data that can be gathered.

Intervention Type
Biological/Vaccine

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Acesso, NeoStim, Surgraft biological/synthetic grafts

Primary outcome measure

The rate of wound healing measured using data documented during every treatment visit (once per week), first is 20% healed, next is 50% compared to week 1, and lastly 100%

Secondary outcome measures
The rate of wound healing measured using data collected every week for a maximum of 10 weeks to achieve wound closure (100%), based on the assumption of one treatment (encounter) per week

Overall study start date
14/02/2023

Completion date
31/03/2030

Eligibility

Key inclusion criteria
1. Aged ≥18 years of age
2. Ulcer or a chronic wound, including an ulcer (diabetic foot ulcer, venous stasis ulcer, etc.), injury (trauma, post-surgical, Mohs surgery treatment), burns injury, and acute/chronic wounds
3. Subject agrees to the use of his health data, including photos of his wound in analysis and publications
4. The subject/subject's legally authorised representative (LAR) must be able to read and understand English and/or Spanish

Participant type(s)
Patient, Population

Age group
Adult

Lower age limit
21 Years

Sex
Both

Target number of participants
4000

Key exclusion criteria
The subject/subject's legally authorised representative (LAR) is unable to read and understand English or Spanish.

Date of first enrolment
01/04/2024

Date of final enrolment
30/06/2029

Locations

Countries of recruitment
United States of America

Study participating centre
Dr Brian Evans
7325 Medical Center Drive, Suite 304
West Hills
United States of America
91307

Sponsor information

Organisation
Siddhey LLC

Sponsor details
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None provided
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Sponsor type
Research organisation

Website
https://www.siddhey.com

Funder(s)

Funder type
Industry

Funder Name
Siddhey LLC

Results and Publications

Publication and dissemination plan
Current plan is to perform QUARTERLY publications starting October 2024, leading up to interim analysis reports at 250 patient marks.

Intention to publish date
14/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Chinmay Chauhan (MBA, RN-BSN, BSBE), ChinmayC@siddhey.com. IPD and analytics will be stored in a secured web server located at https://www.siddhey.com and will only be made available to contracted manufacturers and any healthcare governing bodies.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		08/01/2008	18/06/2024	No	Yes
Protocol file		27/09/2023	18/06/2024	No	No
Other files	Informed Consent Form	10/07/2024	16/07/2024	No	No