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Treatment of pressure ulcers with Algosteril dressing

Submission date
07/09/2021

Recruitment status
No longer recruiting

Registration date
20/10/2021

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Pressure ulcers (also known as pressure sores or bedsores) are injuries to the skin and underlying tissue, primarily caused by prolonged pressure on the skin. They can happen to anyone, but usually affect people confined to bed or who sit in a chair or wheelchair for long periods of time.
In France, pressure ulcers affect approximately 300,000 people of all ages. The prevalence of pressure ulcers in the home, in patients over 65 years of age, was estimated in 2004 to be between 70,000 and 112,000 patients. It is a costly disease that has a significant impact on the quality of life of the person affected.
The prevention and healing of pressure ulcers is a key concern for caregivers. Algosteril dressing can be used for pressure ulcers treatment. Algostéril is a calcium alginate wound dressing, made from seaweed. The study aims is to evaluate wound healing efficacity of dressing Algosteril for treatment of pressure ulcers.

Who can participate?
Patients over 18 years of age with a stage 3 or 4 pressure ulcer can participate in this study.

What does the study involve?
Each patient is treated with Algosteril for 8 weeks at maximum. The dressing is replaced when required (every two days maximum). Pressure ulcer is examined every 2 weeks.

What are the possible benefits and risks of participating?
Algosteril is a dressing that promotes wound healing and also helps to stop bleeding from wounds. No particular risks or constraints were identified for patients participating in this study.

Where is the study run from?
HAD Santé Service (Levallois-Perret) (France)

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

Who is funding the study?
Les Laboratoires Brothier (France)

Who is the main contact?
Melanie Angot, melanie.angot@brothier.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2021-A01344-37

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N° ID-RCB 2021-A01344-37

Study information

Scientific Title
Non-interventional study on the evolution of pressure ulcers treated with Algosteril in Hospital at Home

Acronym
AlgoDOM

Study objectives
A review of the literature over the last 5 years shows that no prospective clinical study evaluating the efficacy of a dressing for pressure ulcers in Hospital at Home has been conducted, although a large number of pressure ulcers are managed by Hospital at Home.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/08/2021, Sud-Est IV Ethics Committee (Centre Léon Bérard, 28 rue Laennec, 69373 Lyon Cedex 08, France; +33 (0)4.78.78.27.61; ppse4@lyon.unicancer.fr), ref: none provided

Study design
Multicenter observational study

Primary study design
Observational

Secondary study design

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participation information sheet

Health condition(s) or problem(s) studied
Stage 3 or 4 pressure ulcer

Interventions
Each patient is treated with Algosteril and followed for a maximum of 8 weeks.
5 protocol visits are planned: Day of inclusion, Week 2, Week 4, Week 6 and Week 8 or Day of cicatrisation. Photo is taken at D inclusion, W2, W4, W6 and W8 or D cicatrisation, and surface of pressure ulcer is calculated at these visits.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Algostéril

Primary outcome measure
Efficacity is evaluated by the average relative reduction of the pressure ulcer surface. Surface is measured in cm^2 at D inclusion, W2, W4, W6 and W8 or D cicatrisation

Secondary outcome measures
1. Efficacy evaluated by the average relative reduction of the pressure ulcer volume. Volume is measured in cm3 at D inclusion, W2, W4, W6 and W8 or D cicatrisation

2. Wound evolution measured using the amount of exudate estimated using a 4-point scale at each visit
3. Quality of peri-wound estimated at each visit using a 2-point scale
4. Presence or not of clinical signs of infection is described at each visit
5. Tolerance measured using adverse events related to Algosteril

Overall study start date
12/08/2021

Completion date
14/11/2023

Eligibility

Key inclusion criteria
1. Patients with stage 3 or 4 pressure ulcer
2. Aged 18 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
97

Key exclusion criteria
Head pressure ulcer

Date of first enrolment
20/09/2021

Date of final enrolment
19/09/2022

Locations

Countries of recruitment
France

Study participating centre

HAD Santé Service
88 rue de Villiers
Levallois-Perret
France
92300

Study participating centre
HAD des Vignes et des Rivières
70 rue des Réaux
Libourne
France
33500

Study participating centre
AUB HAD
32 rue du Grand Jardin
St Malo
France
35400

Study participating centre
HADAN
17 rue du bois de la Champelle
Vandoeuvre les Nancy
France
54500

Study participating centre
HAD Soins et Santé
325 bis rue Maryse Bastié
Rillieux la Pape
France
69141

Study participating centre
HAD LNA Santé Orléans-Montargis
1419 route de Viroy
Amilly
France
45200

Sponsor information

Organisation
Brothier (France)

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Sponsor type
Industry

Website
http://www.brothier.com

ROR
https://ror.org/007jkh405

Funder(s)

Funder type
Not defined

Funder Name
Brothier

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. melanie.angot@brothier.com

IPD sharing plan summary

Available on request