

Treatment of pressure ulcers with Algosteril dressing

Submission date 07/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/10/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2022	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 efficacy 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

Clinical Trials Information System (CTIS)
2021-A01344-37

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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)

Algosténil

Primary outcome(s)

Efficacy is evaluated by the average relative reduction of the pressure ulcer surface. Surface is measured in cm² at D inclusion, W2, W4, W6 and W8 or D cicatrisation

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/007jkh405>

Funder(s)

Funder type

Not defined

Funder Name

Brothier

Results and Publications

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