

Healing efficacy, safety and ease of use of a thin Algostéril

Submission date 11/01/2017	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/01/2017	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 08/08/2018	Condition category Skin and Connective Tissue Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Patients with open wounds often need to be treated with a dressing to help the wound to heal. Algostéril is a calcium alginate wound dressing, made from seaweed. It works by providing a moistened environment for the wound which helps the healing process. This study is looking at a new form of Algosteril, narrower than Algosteril, commonly used by surgeons. The aim of this study is to find out whether this new shape of Algosteril, which can better adapt to the shape of wounds, can help improve wound healing.

Who can participate?

Adults with a wound that needs dressing.

What does the study involve?

Each patient is treated using Algostéril dressings until their wound is healed. The dressing is replaced when required (every two days maximum) until it is no longer required. The length of wound healing is around one month, however this may vary depending on the patient. The wound is examined every time the dressing is changed in order to look for any signs of infection and to record the length of time taken for the wound to heal.

What are the possible benefits and risks of participating?

The potential benefits to participating in this study include quick wound healing, using a dressing that is easy to use and remove. There are no notable risks involved with participating in this study.

Where is the study run from?

1. Pitié-Salpêtrière Hospital (France)
2. CHU Estaing (France)
3. Centre François-Xavier Michelet (France)
4. Jean Minjoz Hospital (France)

When is the study starting and how long is it expected to run for?

February 2016 to December 2017

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

Who is the main contact?
Dr Mueser Maryse

Contact information

Type(s)
Scientific

Contact name
Dr Maryse Mueser

Contact details
Les Laboratoires Brothier
41 rue de Neuilly
Nanterre
France
92735

Additional identifiers

Protocol serial number
N°ID RCB : 2016-A00101-50

Study information

Scientific Title
Healing efficacy, safety and ease of use of a thin Algostéril in the wounds of maxillofacial surgery

Study objectives
The aim of the study is to demonstrate the efficiency of thin Algostéril in wounds of the head and the neck.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Persons Protection Committee, CPP Ile-De-France VI, 16/03/2016, ref: CPP/7-16

Primary study design
Interventional

Study design
Multi-centre prospective non-randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Wound care

Interventions

All patients have their wounds treated using an Algostéril dressing until wound healing (about one month). Wounds will be redressed every two days maximum. Participants are clinically examined in order to determine the number of days until wound healing occurs. There will be no follow up post-healing.

Intervention Type

Other

Primary outcome(s)

Number of days of treatment to obtain the wound healing is assessed through clinical examination until time of wound healing (approximately 1 month).

Key secondary outcome(s)

1. Draining efficiency evaluated by exudate quantity and local signs of infection at the time of redressing (every 2 days maximum)
2. Ease of use is assessed using a scale of 1 to 4 at the time of redressing (every 2 days maximum)
3. Safety is assessed by recording the type and frequency of adverse events continuously throughout the study

Completion date

31/05/2019

Eligibility**Key inclusion criteria**

1. Patients with a wound that needs to be treated with thin Algostéril
2. Those who can be followed until the wound healing
3. Signed informed consent form
4. Aged 18 years and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnant women
2. Participation in another clinical trial within 30 days prior to inclusion

Date of first enrolment

16/01/2017

Date of final enrolment

30/04/2019

Locations

Countries of recruitment

France

Study participating centre**Pitié-Salpêtrière Hospital**

47-83 Boulevard de l'Hôpital

Paris

France

75013

Study participating centre**CHU Estaing**

1 Rue Lucie Aubrac

Clermont-Ferrand

France

63100

Study participating centre**Centre François-Xavier Michelet**

Place Amélie Raba-Léon

Bordeaux

France

33076

Study participating centre**Jean Minjoz Hospital**

3 Boulevard A. Fleming

Besançon

France

25030

Sponsor information

Organisation

Les Laboratoires Brothier

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Les Laboratoires Brothier

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date