

Efficacy, safety and ease of use of a thin Algostérial in the local care of wounds

Submission date 04/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/01/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/02/2022	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Algostérial 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 looks at how effective the dressing is at healing wounds.

Who can participate?

Adults with a wound that needs dressing.

What does the study involve?

Each patient is treated with a Algostérial dressing until their wound is healed.

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. No risks have been identified.

Where is the study run from?

CHU Amiens-Picardie (University Hospital Centre) (France)

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

June 2015 to December 2015

Who is funding the study?

Laboratoires Brothier (France)

Who is the main contact?

Dr Mueser Maryse

Contact information

Type(s)

Scientific

Contact name

Dr Mueser Maryse

Contact details

Les laboratoires Brothier
41 rue de Neuilly
Nanterre
France
92735

Additional identifiers**Protocol serial number**

n°ID RCB 2015-400810-49

Study information**Scientific Title**

Efficacy, safety and ease of use of a thin Algosténil in the local care of wounds: a monocentric prospective study

Study objectives

The aim of this study is to demonstrate that a thin Algosténil is effective at wound healing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Persons Protection Committee (Comité de Protection des Personnes) CPP Nord-Ouest II, 25/09 /2015, ref: 2015 / 44

Study design

Monocentric prospective study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Wounds

Interventions

Each patient is treated with a Algosténil dressing until wound healing in about one month.

Intervention Type

Other

Primary outcome(s)

Number of days of treatment to obtain the wound healing, checked by the methylene blue test

Key secondary outcome(s)

1. Ease of use
2. Assessment of safety throughout the trial

Completion date

31/01/2020

Eligibility

Key inclusion criteria

Patient :

1. aged 18 years or older
2. with a wound that needs to be treated by a thin Algosténil
3. who can be followed until the wound healing
4. who signed informed consent form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Participant or participating in another clinical trial within 30 days prior to inclusion

Date of first enrolment

04/12/2015

Date of final enrolment

04/12/2016

Locations

Countries of recruitment

France

Study participating centre

CHU Amiens-Picardie (University Hospital Centre)

France

80054

Sponsor information

Organisation

Les laboratoires Brothier

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Brothier pharmaceutical laboratory

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for this 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			22/02/2022	No	No