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

Submission date
11/01/2017

Recruitment status
No longer recruiting

Registration date
19/01/2017

Overall study status
Completed

Last Edited
08/08/2018

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
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
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France
92735

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multi-centre prospective non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures
1. Draining efficiency evaluated by exsudate 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

Overall study start date
01/02/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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

Sponsor details
41 rue de Neuilly
Nanterre
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92735

Sponsor type
Industry

ROR
https://ror.org/007jkh405

Funder(s)

Funder type
Industry

Funder Name
Les Laboratoires Brothier

Results and Publications

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

Intention to publish date
31/03/2020

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