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

Submission date	Recruitment status
04/01/2016	No longer recruiting
Registration date	**Overall study status**
06/01/2016	Completed
Last Edited	**Condition category**
22/02/2022	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
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 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 Algostéril 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
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Nanterre
France
92735

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
n°ID RCB 2015-400810-49

Study information

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

Study objectives
The aim of this study is to demonstrate that a thin Algostéril 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

Secondary study design

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Wounds

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

Intervention Type
Other

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

Secondary outcome measures
1. Ease of use
2. Assessment of safety throughout the trial

Overall study start date
12/06/2015

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 Algostéril
3. who can be followed until the wound healing
4. who signed informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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

Sponsor details
41 rue de neuilly
Nanterre
France
92735

Sponsor type
Industry

ROR
https://ror.org/007jkh405

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
All study results will be published in the same publication.

Intention to publish date
01/03/2020

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