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Assessment of pain when withdrawal of Negative Pressure Wound Therapy: Algostéril + Foam vs Foam only

Submission date 16/02/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/02/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/10/2015	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Negative-pressure wound therapy (NPWT) is a technique which uses a vacuum dressing to promote healing in acute or chronic wounds. The aim of this study is to compare two treatment sequences involving Algosteril.

Who can participate?
Adults treated by NPWT for 7 days and who need to be treated by NPWT for another 4 days minimum. They must be able to self-assess their pain.

What does the study involve?
Participants will be randomly allocated to one of two sequences:
Sequence A = Treatment at day 0 = Foam + Algostéril; Treatment at day 2 = Foam only
Sequence B : Treatment at day 0 = Foam only; Treatment at day 2 = Foam + Algostéril

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
A number of French hospitals. The lead centre is CHU La Milétrie, Poitiers (France).

When is the study starting and how long is it expected to run for?
From October 2014 to April 2015

Who is funding the study?
Laboratoires Brothier (France)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014-A00247-40

Study information

Scientific Title
A randomized clinical trial assessing the pain when withdrawal of Negative Pressure Wound Therapy: Algostéril + Foam vs Foam only

Study objectives
Demonstrate that pain is alleviated by Algostéril.

Ethics approval required
Old ethics approval format

Ethics approval(s)
French Ethics Committee (Comité de Protection des Personnes Ouest III), 02/06/2014.
French Drug Administration (Agence Nationale de Sécurité du Médicament), 11/04/2014.
Protocol N°14.03.18.

Study design
Multicentre prospective randomized cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Patient with loss of wound exudate that needs to be treated with Negative Pressure Wound dressing.

Interventions
After 7 days of Negative Pressure Wound dressing, randomisation is performed in a 1:1 ratio allocation.
According to the randomisation sequence, patient has to be treated with Algostéril + Foam during 2 days then he/she has to be treated with the foam only during 2 days or patient has to be treated with the foam only during 2 days then he/she has to be treated with Algostéril + foam during 2 days.

Intervention Type
Other

Primary outcome measure
Assessment of pain using a scale from 0 to 10 at day 2 and day 4

Secondary outcome measures
1. Assessment of bleeding with a 5-level scale - day 2 and day 4
2. Quantity of exudate in the Negative Pressure Wound Dressing reservoir - day 2 and day 4
3. Assesment of safety - throughout the trial

Overall study start date
07/10/2014

Completion date
07/04/2015

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Who have wound exudate treated with Negative Pressure Therapy for 7 days and whose treatment with Negative-Pressure Wound Therapy with black foam and without instillation needs to be continued for a minimum of 4 days
3. Able to self-assess pain
4. Can be followed during the 4 days of the study
5. Signed informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Exudate resulting from a burn
2. Under analgesic level III
3. With known diabetic neuropathy
4. Negative-Pressure Wound Therapy which is contraindicated according to Haute Autorité de Santé (HAS) recommendations
5. Participant or participating in another clinical trial within 30 days prior to inclusion

Date of first enrolment
07/10/2014

Date of final enrolment
07/04/2015

Locations

Countries of recruitment
France

Study participating centre
CHU La Milétrie
Poitiers
France
86021

Study participating centre
Hôpital Saint Louis
Paris
France
75475

Study participating centre
CHU Hôpital Jean Minjoz
Besançon
France
25000

Study participating centre
CHU La Rochelle-Ré-Aunis
France
17019

Study participating centre
CHU Amiens - Picardie
Amiens
France
80054

Study participating centre
CHU Hôpital Central
Nancy
France
54035

Study participating centre
Hôpital Avicenne
Bobigny
France
93000

Study participating centre
Centre Hospitalier du Pays d'Aix
Aix en Provence
France
13617

Sponsor information

Organisation
Brothier Laboratoires

Sponsor details
41 rue de Neuilly
Nanterre
France
92735

Sponsor type
Industry

ROR
https://ror.org/007jkh405

Funder(s)

Funder type
Industry

Funder Name
Brothier Laboratoires

Results and Publications

Publication and dissemination plan
All study results will be published in the same publication in 05/2016.

Intention to publish date
31/05/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available