

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 Algostéril.

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?

Mélanie Angot

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Contact information

Type(s)

Scientific

Contact name

Prof Louis-Etienne Gayet

Contact details

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Multicentre prospective randomized cross-over study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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. Assessment of safety - throughout the trial

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

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

Funder(s)

Funder type
Industry

Funder Name

Brothier Laboratoires

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available