

# Comparison of the efficacy, tolerance and cost of Algostéril vs Negative Pressure Therapy in preparation for skin grafting following surgical excision

<b>Submission date</b> 16/02/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/03/2023	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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 how to compare the Algosteril product to negative-pressure wound therapy in preparation for skin grafting following surgical excision.

### Who can participate?

Adults scheduled for surgical removal with a granulation phase (a phase of the wound healing process) before a skin graft.

### What does the study involve?

Participants will be randomly allocated to one of two groups: NPWT or Algosteril.

### 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 Hopital St Louis, Paris.

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

From July 2014 to December 2015

### Who is funding the study?

Laboratoires Brothier (France)

### Who is the main contact?

Sandra Kolb

[kolb@brothier.com](mailto:kolb@brothier.com)

# Contact information

## Type(s)

Scientific

## Contact name

Dr Marc Revol

## Contact details

Hôpital Saint-Louis

Service de Chirurgie plastique, reconstructrice et esthétique

1 Avenue Claude Vellefaux

Paris

France

75010

# Additional identifiers

## Protocol serial number

EXE-ALG/TPN-06.2013

# Study information

## Scientific Title

Comparison of the efficacy, tolerance and cost of Algostéril vs Negative Pressure Therapy in preparation for skin grafting following surgical excision: a multicentre prospective randomised parallel group trial

## Acronym

ATEC

## Study objectives

The granulation phase can be supported by medical devices including Algosteril and Negative Pressure Therapy which are most commonly used, with good results. The study will demonstrate the non-inferiority of both treatments to obtain an optimal granulation tissue to receive a thin skin graft.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

French Ethics Committee (CPP Ile de France IV) 15/07/2013, ref 2013/22SC

## Study design

Multicentre prospective randomised parallel group trial

## Primary study design

Interventional

**Study type(s)**

Treatment

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

Surgical removal with a granulation phase before a skin graft supported in restorative, reconstructive and plastic surgery service

**Interventions**

Surgical excision of the skin and underlying tissues are carried out in plastic surgery for tumor traumatic or infectious causes. If the resulting defect is well vascularized, it can be covered by a thin skin graft immediately or just after a granulation phase.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Time to optimal granulation. After excision, evaluation for grafting every 7 days and until the wound can receive skin graft.

**Key secondary outcome(s))**

1. Care costs: at each dressing change
2. Patient quality of life: every 7 days and until the wound can receive skin graft.
3. Tolerance: thought the trial

**Completion date**

10/09/2016

**Eligibility****Key inclusion criteria**

1. Written informed consent
2. Patients aged 18 years or older
3. Scheduled for surgical removal with a granulation phase before a skin graft

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

**Key exclusion criteria**

1. Uncontrolled hyperglycemia
2. Excision is secondary to burns
3. Treated within 30 days before enrollment with immunosuppressants, chemotherapy, radiotherapy on the site excised,

**Date of first enrolment**

02/07/2014

**Date of final enrolment**

30/06/2016

**Locations****Countries of recruitment**

France

**Study participating centre**

**Hôpital Croix Rousse**

Lyon

France

69000

**Study participating centre**

**Hôpital Civil**

Strasbourg

France

67000

**Study participating centre**

**Hôpital La Conception**

Marseille

France

13000

**Study participating centre**

**Hôpital Saint-Roch**

Nice

France

06000

**Study participating centre**  
**CHU Angers**  
Angers  
France  
49000

**Study participating centre**  
**Hôpital Hôtel Dieu**  
Nantes  
France  
44000

**Study participating centre**  
**La Cavale Blanche**  
Brest  
France  
29000

**Study participating centre**  
**CHU Lille**  
Lille  
France  
59000

**Study participating centre**  
**CHU Bordeaux**  
Bordeaux  
France  
33000

**Study participating centre**  
**Hôpital Saint-Louis**  
Paris  
France  
75010

**Study participating centre**

**Hôpital Saint-Antoine**

Paris

France

75012

**Study participating centre****CHU Nancy**

Nancy

France

54000

**Study participating centre****CHU Amiens**

Amiens

France

80000

**Study participating centre****Hôpital Jean Minjoz**

Besançon

France

25000

**Study participating centre****CHU Rennes**

Rennes

France

35000

**Sponsor information****Organisation**

Laboratoires Brothier

**ROR**

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

# Funder(s)

## Funder type

Industry

## Funder Name

Laboratoires Brothier

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Marc Revol (mrevol05@gmail.com).

Type of data : Individual participant data that underlie the results reported in the article after anonymisation and the study protocol

When the data will become available and for how long: Beginning 9 months and ending 36 months following article publication

By what access criteria data will be shared including with whom: To investigators whose proposed use of the data has been approved by the corresponding author and the sponsor

For what types of analyses: Meta-analysis

By what mechanism: Proposals should be directed to the corresponding author (mrevol05@gmail.com) up to 36 months following article publication. To gain access, data requestors will need to sign a data access agreement. An accessing data link will be created to recipients

Whether consent from participants was obtained: Consent from participants was obtained and restricts the data access to the French health authorities

Comments on data anonymization: Data were anonymized (Patient number from 1 to 113)

Ethical or legal restrictions: From 2018, the EU General Data Protection Regulation (GDPR) restricts transfers of personal data to countries outside the EEA.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		27/03/2020	08/03/2023	Yes	No
<a href="#">Basic results</a>		31/07/2019	21/07/2021	No	No