

# Effectiveness of TRIONIC compresses to stop abdominal oozing after deep inferior epigastric perforator breast reconstruction surgery

<b>Submission date</b> 17/04/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/06/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Breast reconstruction using the deep inferior epigastric perforator (DIEP) technique involves removing a piece of skin and fat from the abdominal region, as well as blood vessels (flap). This flap is placed in the thorax and the vessels of the flap are connected to the vessels of the thorax. The irrigated flap is then shaped to look like a natural breast. In the area where the flap has been harvested (donor site), electrocoagulation (conventional vessel closure technique) is used to limit haemorrhagic oozing (small flows of lymph and blood). Then drains (tubes) connected to bottles are placed in the abdominal area and the donor site is closed. The abdominal drains are used to drain off any haemorrhagic ooze that may accumulate after surgery. If these fluids are not drained, they can lead to complications such as seromas (accumulation of lymph) or haematomas (accumulation of blood), which delay healing. Drains are removed as soon as there is no or very little fluid to drain. TRIONIC compresses are indicated to reduce haemorrhagic oozing. The aim of this study is to demonstrate the effectiveness of TRIONIC in reducing haemorrhagic oozing at the flap donor site.

### Who can participate?

Women aged over 18 years having DIEP flap reconstruction

### What does the study involve?

Patients will be randomly assigned to either the TRIONIC group (TRIONIC is used on the donor site after electrocautery) or the control group (electrocautery alone). After surgery, the daily volume of abdominal fluid drained and the duration of the abdominal drain are noted. Abdominal complications are monitored for 3 weeks after surgery.

### What are the possible benefits and risks of participating?

Participants may benefit from a decrease in drain duration and in the volume of fluid drained. No risks have been identified.

Where is the study run from?

A number of French hospitals. The lead centre is Hopital Européen Georges Pompidou, Paris (France)

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

January 2022 to February 2024

Who is funding the study?

Laboratoires Brothier (France)

Who is the main contact?

Laurent Lantieri, laurent.lantieri@aphp.fr

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Laurent Lantieri

### Contact details

Hôpital Européen Georges Pompidou, APHP  
Chirurgie plastique reconstructrice et esthétique  
20 rue Leblanc  
Paris  
France  
75015  
+33 (0)1 56 09 53 20  
laurent.lantieri@aphp.fr

## Additional identifiers

### Clinical Trials Information System (CTIS)

2022-A02571-42

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

DIEP-TRIOc-11.2022

## Study information

### Scientific Title

Efficacy of TRIONIC after electrocautery vs electrocautery alone in controlling haemorrhagic oozing from the deep inferior epigastric perforator flap donor site - a multicenter randomized clinical investigation

### Acronym

TRIOD

### **Study objectives**

It is hypothesized that TRIONIC could reduce haemorrhagic oozing postoperatively.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 01/02/2023, CPP Sud Est 1 (CPP: Comité de protection des personnes = protection committee for people (involved in the study)) (CHU - Hôpital Bellevue DAMR - pavillon 31, 42055 Saint-Étienne Cedex 2, France; +33 (0)4 77 12 70 08; cpp.sudest1@chu-st-etienne.fr), ref: not applicable

### **Study design**

Multicentre prospective randomized study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Female adult patients having breast reconstruction with deep inferior epigastric perforator (DIEP) flap

### **Interventions**

Patients are randomized (Interactive Web Response System [IWRS]) during surgery after electrocautery of the abdominal area. According to the randomization, patient will be treated with TRIONIC or not. TRIONIC will be applied and maintained in place until the bleeding stops. TRIONIC will be removed before closing the surgical site. Duration of follow-up: 21 days (+/- 3 days).

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

TRIONIC (alginate)

### **Primary outcome(s)**

Number of days of abdominal drainage from placement of the abdominal drains until a volume of 20 ml/24 h is in each of the two drainage bottles

### **Key secondary outcome(s)**

1. Total volume of abdominal drainage fluid collected in the two drainage bottles from placement of the drains until a drainage volume  $\leq 20$  ml/24 h is achieved in each of the two bottles

## 2. Postoperative abdominal complications:

- 2.1. Percentage of patients with seroma and % of patients with haematoma during 21 days of follow-up
- 2.2. Percentage of patients with unhealed abdominal suture at 21 days after surgery
3. Tolerance: nature and frequency of TRIONIC-related incidents and adverse events (AEs) related to the investigation procedure

## Completion date

27/02/2024

# Eligibility

## Key inclusion criteria

1. Women aged 18 years or over
2. Undergoing unilateral or bilateral DIEP flap breast reconstruction
3. Having read and understood the patient information sheet and signed a written informed consent
4. Affiliated to the French social security system ("Sécurité sociale")

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

Female

## Total final enrolment

40

## Key exclusion criteria

1. Patients with hemophilia, with Willebrand or Rendu-Osler disease or on long-term anticoagulant/antiplatelet treatment
2. Known to be allergic to the components of TRIONIC
3. End of hospitalization planned before the end of abdominal drainage
4. Might not return for the end-of-study visit
5. Under legal protection and/or unable to give written informed consent herself
6. Participating or going to participate or having taken part simultaneously in another trial which could have an impact on haemorrhagic oozing in the abdominal layer

## Date of first enrolment

27/04/2023

**Date of final enrolment**

08/02/2024

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

France

**Study participating centre****Hôpital Européen Georges Pompidou**

Chirurgie plastique reconstructrice et esthétique

20 rue Leblanc

Paris

France

75015

**Study participating centre****Hôpital Tenon**

Chirurgie plastique reconstructrice et esthétique

4 Rue de la Chine

Paris

France

75020

**Study participating centre****Hôpital de la Conception**

Chirurgie plastique et réparatrice

147 Bd Baille

Marseille

France

13005

**Study participating centre****Hôpital Rangueil**

Chirurgie plastique, reconstructrice et esthétique

1, avenue du Pr Jean Poulhès

Toulouse

France

31400

**Study participating centre**

## Hôtel Dieu

Chirurgie plastique, reconstructrice et esthétique  
1 Place Alexis-Ricordeau  
Nantes  
France  
44000

## Sponsor information

### Organisation

Brothier (France)

### ROR

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

## Funder(s)

### Funder type

Industry

### Funder Name

Brothier (France)

## Results and Publications

### Individual participant data (IPD) sharing plan

The 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		24/06/2025	24/06/2025	No	No