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

Submission date
17/04/2023

Recruitment status
No longer recruiting

Registration date
18/04/2023

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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 ≤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?
Basic results		24/06/2025	24/06/2025	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes