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

Submission date
16/02/2015

Recruitment status
No longer recruiting

Registration date
23/02/2015

Overall study status
Completed

Last Edited
08/03/2023

Condition category
Surgery

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

Type(s)
Scientific

Contact name
Dr Marc Revol

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 after a granulation phase.

Intervention Type
Procedure/Surgery

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

Secondary outcome measures
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

Overall study start date
02/01/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
112

Total final enrolment
95

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

Sponsor details
41, rue de Neuilly
Nanterre
France
92735

Sponsor type
Industry

ROR
https://ror.org/007jkh405

Funder(s)

Funder type
Industry

Funder Name
Laboratoires Brothier

Results and Publications

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

Intention to publish date
31/12/2020

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?
Basic results		31/07/2019	21/07/2021	No	No
Results article		27/03/2020	08/03/2023	Yes	No