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Healing effectiveness of Algosteril vs Aquacel Extra in pilonidal sinuses

Submission date
27/07/2023

Recruitment status
Recruiting

Registration date
28/07/2023

Overall study status
Ongoing

Last Edited
04/04/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pilonidal disease is caused by the penetration of hairs into dimples in the gluteal (buttock) cleft and may present as an acute abscess or chronic suppuration (pus). In the chronic phase, surgery is recommended. The technique of wide excision without closure is favoured by French surgeons: under anaesthesia, the infected tissue is removed, then the wound is left open for directed healing (budding tissue develops and fills the lesion from depth to surface). Wide excision of the pilonidal sinus has a 95% recurrence-free cure rate. However, it is a high-impact procedure for patients, requiring daily, sometimes painful nursing care over a prolonged period (typically 2-3 months). The aim of this study is to demonstrate that the speed of budding tissue development is faster with Algosteril compared with Aquacel Extra.

Who can participate?
Patients with a pilonidal sinus that needs to be excised

What does the study involve?
Patients will be randomly assigned to either the Algostéril group or the Aquacel Extra group. After surgery, the excision filling will be evaluated at weeks 3 and 6.

What are the possible benefits and risks of participating?
Participants treated with Algostéril may benefit from a reduction of the duration of healing. No risks have been identified. Algosteril and Aquacel Extra will be used as indicated.

Where is the study run from?
The study will be run from several French hospitals

When is the study starting and how long is it expected to run for?
December 2022 to July 2026

Who is funding the study?
Laboratoires Brothier (France)

Who is the main contact?
Mélanie Angot, melanie.angot@brothier.com

Contact information

Type(s)
Public

Contact name
Mrs Mélanie Angot

Contact details
Brothier
41 rue de Neuilly
Nanterre
France
92735
+33 (0)1 56 38 30 00
recherche.clinique@brothier.com

Additional identifiers

EudraCT/CTIS number
2022-A02722-41

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RCT/PILO-ALGm/ALGc-12.2022

Study information

Scientific Title
Multicenter, prospective, randomized clinical trial evaluating the healing efficacy of Algosteril® vs Aquacel Extra® in complete pilonidal sinus excisions

Acronym
ALPI

Study objectives
Algostéril is better than Aquacel Extra for the healing of the pilonidal sinus excision

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/04/2023, CPP Nord-Ouest IV (Bâtiment ex USNB- 6 rue du Pr Laguesse - CHRU Lille - CS70001, Lille, 59037, France; -; cppnordouestiv@univ-lille.fr), ref: 22.04704.000166

Study design
Multicenter prospective comparative randomized parallel-group open-label superiority study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Care home, Hospital

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in the web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pilonidal sinus

Interventions
Patients were randomized (Interactive Web Response System [IWRS]) during surgery after excision of the pilonidal sinus. According to the randomization, patients will be treated with Algostéril or Aquacel Extra. The dressing will be renewed by the nurse at the patient’s home in accordance with the note to use. The duration of follow-up will be 6 weeks.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Algostéril, Aquacel Extra

Primary outcome measure
% of patients with complete excisional closure evaluated by the investigator at 6 weeks post-operative

Secondary outcome measures

1. % reduction of the excision volume measured by depth x area at weeks 3 and 6
2. Time in days between the date of surgery and resumption of normal activity, self-assessed by patient
3. Nature and frequency of Algostéril or Aquacel Extra-related incidents and adverse events (AEs) related to the investigation procedure, recorded using the adverse event form throughout the study

Overall study start date
15/12/2022

Completion date
01/07/2026

Eligibility

Key inclusion criteria
1. Adult with sacrococcygeal pilonidal sinus:
1.1. Non-recurrent
1.2. Who must undergo excision down to the fascia with an electric scalpel
1.3. With an excision length of between 5 and 12 cm
1.4. Which will be left to undergo directed healing
2. Which may be seen again as an outpatient at weeks 3 and 6
3. Affiliated with a social security scheme
4. Who have read and understood the information note and signed a written informed consent to participate in the clinical investigation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
238

Key exclusion criteria
1. Pilonidal sinus requiring simple flattening and/or with associated anal fistula
2. Verneuil disease and/or uncontrolled diabetes (> 2g/l)
3. Treated with long-term anti-inflammatory drugs, chemotherapy or immunocompromised
4. Undergoing or having undergone pelvic radiotherapy
5. Known to be allergic to constituents of study products
6. Concurrently participating in another study that may have an impact on wound healing
7. Pregnant or nursing woman

8. Person deprived of liberty by judicial or administrative decision or person subject to a legal protective measure

Date of first enrolment
01/08/2023

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
France

Study participating centre
GH Paris St Jospeh
185 rue Raymond Losserand
Paris
France
75014

Study participating centre
Clinique Blomet
136bis rue Blomet
Paris
France
75015

Study participating centre
GH Diaconnesses Croix St Simon
125 rue d'Avron
Paris
France
75020

Study participating centre
HIA Begin
69 avenue de Paris
saint Mandé
France
94160

Study participating centre
CU Grenoble Alpes
boulevard de la Chantourne
La Tronche
France
38700

Study participating centre
HIA Clermont-Tonnerre
Rue Colonel Fonferrier
Brest
France
29240

Study participating centre
MSP Bordeaux Bagatelle
203 route de Toulouse
Talence
France
33401

Study participating centre
Cabinet de proctologie
5 route de St Nazaire
Saint Herblain
France
44800

Study participating centre
CHI Poissy St Germain en Laye
10 rue du Champ Gaillard
Poissy
France
78303

Sponsor information

Organisation
Brothier (France)

Sponsor details
41 rue de Neuilly
Nanterre
France
92735
+33 (0)1 56 38 30 00
Recherche.clinique@brothier.com

Sponsor type
Industry

Website
http://www.brothier.com

ROR
https://ror.org/007jkh405

Funder(s)

Funder type
Industry

Funder Name
Brothier (France)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2025

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