

# Healing effectiveness of Algosteril vs Aquacel Extra in pilonidal sinuses

<b>Submission date</b> 27/07/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/04/2025	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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## 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 Diaconesses 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**

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**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