Patient < 21 yrs old with symptomatic PD, upon first contact with surgeon

Enrollment

Surgeon Choice

Primary Surgical Management

Surgeon Choice

Gips

Early Gips Endpoint

Wide Excision

Early WLE Endpoint

Observation

Yes

Heal

No

Surgery

Non-Operative Endpoint

Patient Choice

Recurrence

Gips

Failed MM + Gips Endpoint

Wide Excision

Failed MM + WLE Endpoint

Pilonidal Study Algorithm
PIOLONIDAL PATHWAY
-A Medical Management Guideline for Pilonidal Disease-

HAIR MANAGEMENT
Shaving, cream epilation, waxing, or laser hair removal for hair-free skin.

HYGIENE MEASURES
Bath or shower at least daily to keep the area clean.

OTHER RECOMMENDATIONS
Use antibacterial soap.
Remove hair from wound.
Keep the area dry.
Avoid tight-fitting clothes.
Avoid prolonged sitting.

THE GIPS PROCEDURE
-A Step-By-Step Guide for Pilonidal Disease Excision-

SKIN PREPARATION
The area is cleaned and shaved.

LOCAL ANESTHESIA
The skin is numbed with an injection.

CORING OF TRACTS
The tunnels are opened with a special punch.

WOUND DEBRIDEMENT
The tissue is scraped with a curette.

WOUND CLEANSING
The wounds are cleaned with peroxide.

TIME FOR HEALING
Small holes are left open to heal.
2019-0832: MWPSC Pilonidal Study

- Submitted: 6/19/2019
- Approved: 7/22/2019
- Effective: 8/29/2019
- Enrollment: 8/30/2019
- End: 7/21/2022
Participant

Research Team

+Research Visit Checklist ✓
+Informed Consent Checklist ✓
Medical Management Arm Consensus

• The following interventions will be considered **standard**:  
  – Hair clipping by provider at first encounter, followed by shaving or cream epilation by patient or caregiver.  
  – Shower or bathing at least 1/day.

• The following interventions will be considered **optional**:  
  – Hibiclens or antibacterial soap.  
  – Antibiotics (choice and duration).  
  – Tweezer hair removal from pits.  
  – Avoid tight clothing, keep the area clean and dry, and minimize sitting.
Failure of medical management

- Determined by patient satisfaction.
- Suggest at least 4 weeks/30 days.
- Recommend surgery at 2 months if non-progressing to healing.

Recurrence

Episode of active pilonidal disease requiring medical or surgical intervention (as defined by topical medication, antibiotics, incision and drainage, or excision)
- after a recorded period of healing, significant clinical improvement, or patient satisfaction
- with a minimum of 1 prior intervention for pilonidal disease (including medical management)
- and a minimum of 30 days from the initiation of the preceding treatment.
Research Follow Up

Independent of clinical follow up and will be completed online and by phone.

*Patient incentives = $100 total (ClinCard).
*APSA Foundation Grant: $25,000.
Experience

• Research team approaches after MD visit.
• Takes 5-7 minutes per patient.
• 100% have agreed before even mentioning payment.
• Have not struggled with W-9s; mention no 1099 involved.
• Some patients uncomfortable answering the “feeling” questions with parents looking over their shoulder.
• Identified need for journal or diary form to keep track of pain, healing, return to activities for more accurate data for 1-month follow up.
Hybrid GIPS – Sinus Endoscopy

Karl Storz EPSIT equipment unavailable in U.S.
Only being done right now at CCHMC
Hybrid GIPS – Sinus Endoscopy
Pilonidal Disease – The Midwest Pediatric Surgery Consortium Project

Presented by Nelson G. Rosen MD
Beth A. Rymeski, DO – Principle Investigator
Alejandra M. Casar Berazaluce, MD – Research Fellow
Rebeccah L. Brown, MD – Co-Investigator

2nd International Pilonidal Sinus Disease Conference
28 September 2019, Vienna, Austria