ARTICLE:

• Citation:

  • Funding Sources: EMF EMBRS grant 2007-2008 and the SurgeonGeneral’s Office.

PURPOSE:

• Research Question(s):
  In ED adults with soft tissue abscesses, we evaluated whether trimethoprim-sulfamethoxazole reduced the rate of treatment failure by 15% relative to placebo during the 7 days after incision and drainage.  Secondarily, we assessed the rate of new lesion formation within 30 days.

• Hypothesis:
  Null hypothesis is that treatment with Bactrim will not decrease the rate of treatment failure by >15% compared to no abx and that it will also not reduce the rate of new abscess formation within 30 days.

DESIGN:

• Study Design:
  multicenter, double-blind, randomized, placebo-controlled trial

• Dependent / outcome Variable(s):
  Primary outcome: “treatment failure” within 7 days, defined as no improvement after 2 days, development of a new separate lesion within 7 days, or worsening infection within 7 days, leading to an intervention (ie, further antibiotic administration, additional incision and drainage, surgical debridement, or hospital admission).
  Secondary outcome: development of new lesions, abscess or pustule, within 30 days of enrollment

• Independent / research Variable:
  Treatment with Bactrim

SETTING / SUBJECTS:

• Research Setting:
4 military EDs that treat both civilians and military patients: Wilford Hall Medical Center (50,000 visits/year), Brooke Army Medical Center (50,000 visits/year), Darnall Medical Center (43,000 visits/year), and Portsmouth Medical Center (75,000 visits/year).

- **Subjects:**
  - **Study population:**
    adults (aged 16 years or older) with uncomplicated skin abscesses requiring incision and drainage
  - **Inclusion / Exclusion criteria:**
    Immunocompromised (e.g., diabetes, HIV, cancer), pregnant or breast feeding, allergic to sulfadiazine, had associated fever or signs of systemic illness, had received antibiotics in the previous week, or had been hospitalized in the previous month, abscesses on the face and known or suspected tracts or fistulas to deeper structures, or abscesses requiring operating room drainage.
  - **Number (control / intervention groups):**
    212 subjects: 116 placebo, 96 abx
  - **Demographics:**
    Lots of white males, see table 1
  - **Attrition:**
    For 7-day follow-up, 190 of 212 (90%) subjects were evaluable.
    For the 3 sites collecting 30-day follow-up data, 43 subjects could not be contacted and were lost to follow-up, leaving 96 of 139 (69%) evaluable.

**METHODS:**
- **Interventions:**
  2 Bactrim DS tabs BID x 7days
- **Study Groups:**
  Abx vs placebo
- **Instruments:**
  n/a
- **Data Collection:**
  Treating physicians collect data initially and then study investigators collected follow-up data

**DATA ANALYSIS:**
- **Level of Data:**
  Categorical (two or more categories without order, (ie: male / female)
- **Statistics Used:**
  x^2 or the Fisher’s exact test
- **What, if any, variables were controlled for?**:
  Post hoc sensitivity analyses assuming extreme opposite outcomes for patients lost to follow-up would change the statistical significance of both primary and secondary outcomes

**RESULTS:**
- **Brief answers to research questions:**
  The addition of trimethoprim-sulfamethoxazole (160/800) to incision and drainage did not decrease rates of failure by 15% or more by 7 days compared with placebo. However, it may decrease new lesion development within 30 days.
Limitations:
The principal limitation of this study was the loss to followup. Unequal outcome differences in those not returning or unable to be contacted could have altered our outcomes, particularly the 30-day evaluation.

Convenience sample (did not selectively enroll specific groups). Studied only healthy adults, and thus our findings cannot apply to children or the immunocompromised. Finally, we did not standardize the incision and drainage technique, but rather left clinicians to use their standard practice.

Sample size.

IMPLICATIONS FOR PRACTICE:
• Applicable to this clinical practice:
   Antibiotics are unnecessary after abscess incision and drainage of skin abscesses of non-immunocompromised adults in the ED.

• Feasible (cost, resources, etc):
   This would save money and prevent adverse reactions and growing abx resistance potentially.

• Clinically Relevant:
   Yes

LEVEL OF EVIDENCE / DECISION FOR USE:
• Ready for use

• Level of Evidence:
  Ib Evidence obtained from at least one RCT