Protocol Document for ISRCTN

Study Protocol

Title

Dilute Povidone-Iodine Irrigation Versus Normal Saline Irrigation in Preventing Surgical Site Infection After Appendectomy for Perforated Appendicitis: A Randomized Controlled Trial at a Nigerian Tertiary Hospital

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Background

Surgical site infection (SSI) is a common postoperative complication following appendectomy for perforated appendicitis, particularly in low-resource settings. Perforated appendicitis results in contamination of the operative field with enteric organisms, increasing postoperative morbidity, prolonging hospital stay, and increasing healthcare costs.

Wound irrigation is frequently used during appendectomy to reduce bacterial contamination. Normal saline is commonly used because of its physiological compatibility; however, it lacks antimicrobial activity. Povidone-iodine is a broad-spectrum antiseptic effective against gram-positive and gram-negative bacteria, fungi, and viruses.

Although wound irrigation is widely practiced, there remains limited randomized evidence comparing dilute povidone-iodine irrigation with normal saline irrigation in preventing SSI after appendectomy for perforated appendicitis, particularly in developing countries.

Aim of the Study

To compare the effectiveness of dilute povidone-iodine irrigation versus normal saline irrigation in preventing surgical site infection following appendectomy for perforated appendicitis.

Objectives

Primary Objective

To determine the incidence of surgical site infection within 30 days following appendectomy in both intervention groups.

Secondary Objectives

To compare postoperative readmission rates between both groups.

To compare postoperative reoperation rates between both groups

Study Design

Prospective double-blind randomized controlled trial.

Study Setting

Department of Surgery, University of Port Harcourt Teaching Hospital, Port Harcourt, Nigeria.

Study Duration

February 2017 to January 2018.

Participants

Inclusion Criteria

Adult patients aged 17–70 years.

Diagnosis of perforated appendicitis.

Patients undergoing appendectomy.

Patients able to provide informed consent.

Exclusion Criteria

Uncomplicated appendicitis.

Known iodine sensitivity.

Thyroid disease.

Renal disease.

Patients undergoing interval appendectomy.

Patients unable to provide informed consent.

Randomization

Eligible participants were randomized using sealed opaque envelopes containing treatment allocations.

Participants were assigned into:

Group A: 500 ml of 1% dilute povidone-iodine irrigation.

Group B: 500 ml of 0.9% normal saline irrigation.

Blinding

Patients and postoperative outcome assessors were blinded to treatment allocation. The operating surgeon was aware of the irrigation solution used but was not involved in postoperative assessment.

Intervention

After appendectomy:

Group A wounds were irrigated using 500 ml of 1% dilute povidone-iodine solution.

Group B wounds were irrigated using 500 ml of normal saline solution.

All patients received standard perioperative antibiotics consisting of ceftriaxone