NON-INEFIERIORITY OF SHORT-TERM CATHETERIZATION FOLLOWING SURGERY FOR FEMALE GENITAL FISTULA: A RANDOMIZED CLINICAL TRIAL


1. Fistula Care Project, EngenderHealth, 440 Ninth Avenue, 13th Floor, New York, NY 10001, USA.
2. Fistula Consulting LLC, 452 Union Ave. SE, Grand Rapids, MI 49503, USA
3. World Health Organization, Department of Reproductive Health and Research, 1211 Geneva 27, Geneva, Switzerland
4. L’Hôpital Préfectoral de Kissidougou, Kissidougou, Guinea
5. Aberdeen Women’s Centre, PO Box 416, Freetown, Sierra Leone
6. Gondar University Hospital, Fistula Unit, PO Box 196, Gondar, Ethiopia
8. Kagando Hospital, Kasese District, Uganda
9. National Obstetric Fistula Centre Abakaliki, 1 Water Works Street, Abakaliki, Ebonyi State, Nigeria
10. Kenyatta National Hospital, PO Box 20723-00202, Nairobi, Kenya
11. Maternité Centrale de Zinder, PO Box 463 Zinder, Niger

Objectives: Determine whether outcomes of fistula repair surgery are the same among women with simple fistula who are catheterized for 7 days and those catheterized for 14 days.

Materials and Methods: Fistula Care, World Health Organization, and Program Partners have conducted a facility-based, multicountry, non-inferiority randomized controlled trial (RCT) comparing the new proposed short-term (7-day) urethral catheterization to longer-term (14-day) urethral catheterization among women with simple fistula presenting at study sites for fistula repair service. The primary outcome is fistula repair breakdown up to three months following fistula repair surgery, as assessed by a urinary dye test. Secondary outcomes include repair breakdown one week following catheter removal, intermittent catheterization for urinary retention and the occurrence of septic or febrile episodes, prolonged hospitalization for medical reasons, catheter blockage, and self-reported residual urinary incontinence.

Results: Study recruitment has been completed, and 522 women were randomized to two study arms at eight fistula repair centers across eight countries. Participant follow-up will be completed in August 2013, and detailed results presented at FIGO Regional meeting in October.

Conclusions: If short-term catheterization is revealed to be non-inferior, these findings could lead to increased treatment capacity, lower costs of service, and lower risk of health care-associated infections among women undergoing fistula repair surgery.