EFFECTIVENESS OF PROPHYLACTIC ANTIBIOTIC INTERVENTION (FOSFOMYCIN TROMETAMOL) TO PREVENT URINARY TRACT INFECTIONS (UTI) DUE TO URODYNAMIC STUDIES (UDS) IN WOMEN: A RANDOMIZED CONTROLLED TRIAL

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Ethical approval

The principles of informed consent were implemented in accordance with the ethical principles that have their origin in the Declaration of Helsinki, the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP), and applicable regulatory requirements. The medical ethics committee of the CHR La Citadelle (Agreement 412) gave approval to perform the study. The experimentation was performed according to the guidelines for good clinical practice, publication policy and ethical consideration. The EudraCT number is 2008-007669-21. A contract was subscribed to the insurance company Ethias.

Conflict of interest

This study was partially financed by Zambon Pharma.

Abstract

Introduction

Antibiotics are sometimes used to reduce the incidence of de novo urinary tract infection after urodynamic studies (UDS). This study assessed whether 2 doses of 3 g oral fosfomycin trometamol (Monuril*) (administered to women 3 hours before and 24 hours after UDS) reduced the incidence of significant bacteriuria and clinical signs of urinary tract infection (UTI).

Material and methods

A double-blind randomized controlled trial (RCT) with placebo (EudraCT 2008-007669-21) was conducted. Outcome measures were (1) significant bacteriuria (colony forming unit $>10^5$/ml of clean catch urine), (2) signs of UTI (urgency, dysuria, pollakiuria, suprapubic tenderness, pyrexia, hematuria, pyuria). A per protocol analysis was performed.

Results

Between 2010 and 2012, among 116 eligible patients, 81 were included and randomized. Then 9 were excluded before UDS (positive urinary stick) and 20 were lost to follow up. Women in menopausal status had an increased risk of positive urinary stick ($p = 0.064$). Age, weight, size, body mass index, quality of life, and menopausal status, were not different between the placebo ($n = 27$) and the treatment ($n = 25$) groups. Log-linear analysis retained three parameters (menopause, bacteriuria, Monuril* versus placebo) to explain observed interactions ($\chi^2(7) = 49.34$, $p = 0.000$). When they received Monuril*, none of the patients in menopause developed significant bacteriuria. When they received a placebo, women in menopausal status were 1.6 times (odds ratio) more likely to develop significant bacteriuria than non menopausal women. No patient developed signs of UTI after UDS. No side effect was reported in the placebo group, while two patients developed mild diarrhea in the Monuril* group.

Conclusion

Though the limited sample size should be considered, this study suggests that UTI after UDS is not frequent. It also shows that antibiotic prophylaxy with Monuril might prevent significant bacteriuria in women in menopause.