

**CLINICAL TRIALS OF NIBIOL FORTE
IN PREGNANT WOMEN**

Thesis
Submitted for Partial Fullfilment of
MS Degree in Obstetrics & Gynaecology

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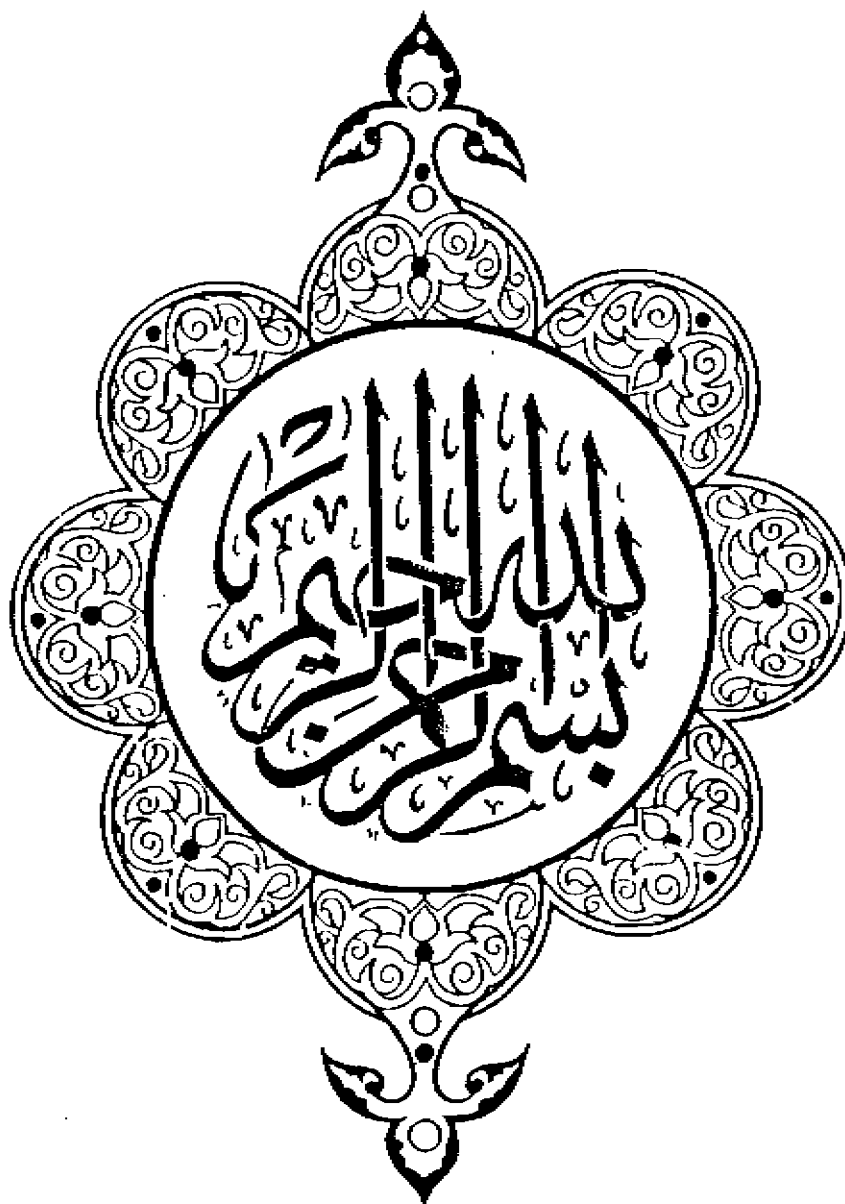
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LIST OF ABBREVIATIONS

ASB	Asymptomatic bacteriuria
UT	Urinary tract
UTIs	Urinary tract infections
E. coli	Escherichia coli
GBS	Group B streptococci
K.	Klebsiella
G. vaginalis	Gardnerella vaginalis
gm+ve	gram positive
gm-ve	gram negative
CFU	Colony forming units
HPF	High power field
IUD	Intra-uterine device
mm.	millimeter
cm.	centimeter
ml.	milliliter
gm	gram
min.	minute
h.	hour
y.	year
No.	number
%	percent
HB%	Haemoglobin percentage.

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INTRODUCTION

AND AIM OF THE WORK

I N T R O D U C T I O N

Asymptomatic Bacteriuria during Pregnancy:-

The term asymptomatic bacteriuria (ASB) implies that a woman without symptoms suggesting urinary tract infection is demonstrated to have a count of 10^5 or more microorganism per ml. of urine (Lannette et al., 1985).

ASB is thought to be responsible for many maternal and foetal complications during pregnancy, prematurity, low birth weight, foetal wastage, foetal congenital anomalies maternal renal impairment, pre-eclampsia, and acute urinary tract infection with its subsequent complications (Pels et al., 1989).

About 20 to 40 percent of untreated cases of ASB ,during the first trimester, develop acute pyelonephritis during the third trimester (Grestner et al., 1989).

Early detection and elimination of ASB should prevent at least two-thirds of all antenatal cases of acute pyelonephritis with its subsequent serious complications (Stenqvist, 1989) and (Harlass and Duff, 1990).

Acute Urinary Tract Infections during Pregnancy:

Lower urinary tract infections (LUTIs) most commonly

acute cystitis, accounts for the second common renal infection during pregnancy (Waltzer, 1981).

Acute cystitis is accompanied with many distressing symptoms to the patients, frequency, nocturia, dysuria, suprapubic tenderness, and sometimes haematuria (Hankins and Whally, 1985).

Whenever the diagnosis of cystitis is made, immediate treatment should begin to prevent upward extension of infection to the kidneys (Harris, 1984).

Acute pyelonephritis is the most common renal complication during pregnancy and occurs in approximately one to two percent of pregnant women, most often in patients with pre-existing bacteriuria (Waltzer, 1981).

Acute pyelonephritis is a serious condition and requires immediate treatment for fear of its complications which may endanger the life of the patient (Harris, 1984).

Nibiol Forte (Nitroxoline):-

A series of oral drugs, effective in the treatment of ASB and LUTIs during pregnancy is now available. The criteria of selection of anti-infectious agent, are apart of its efficacy, its good safety particularly in pregnant women, the absence (or low incidence) of side effects, and lastly its low cost (Frobert and Coupry, 1986).

Nibiol forte, a urinary antiseptic, released into the market in 1962, in France, possesses antibacterial properties on agents most frequently responsible for UTIs, particularly gram-negative bacilli (Courtieu et al., 1979).

Furthermore, it has been recently demonstrated that nitroxoline can inhibit the adhesive properties of uropathogenic strains of E-coli to the uro-epithelial cells which gives it an additional value in prophylaxis of recurrent UTIs (Karam et al., 1986).

Certain pharmacological properties of nitroxoline have been known for a long time such as the rapid urinary elimination in the free form in contrast with a small proportion eliminated by hepatic transformation in conjugated form. Both forms were found to be bacteriologically active. The properties of rapid urinary elimination of nitroxoline has been ensured its recognized place in the treatment of common UTIs (Daoulas et al., 1974).

AIM OF THE WORK

This prospective study will be done to screen women for ASB and LUTIs during pregnancy, to study the prevalence of ASB among pregnant women, to determine the factors that predict the occurrence of both clinical entities during pregnancy, and to find the bacteriological and clinical efficacy of Nibiol Forte in the treatment of ASB and LUTIs during pregnancy.

REVIEW OF LITERATURE