

# Effectiveness and Safety of Isoxsuprine Hydrochloride as Tocolytic Agent in Women with Preterm Labor in India - A Prospective, Observational Study

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## Introduction & Objectives

Preterm labor (PTL) is defined as labor occurring between 20 to 37 gestation weeks. Amongst the developing countries, India has a very **high incidence of PTL (23.3%)**. PTL management utilizes tocolytic therapy to extend gestation which allows usage of corticosteroids and MgSO<sub>4</sub>.

Although  $\beta$ -agonists are extensively used for tocolysis, various studies have reported undesirable safety profiles. Among  $\beta$ -agonists, Isoxsuprine is being used in India for last six decades and **approved by CDSCO** for the management of PTL. Although, **Isoxsuprine is known to be effective, safe and well tolerated tocolytic agent**, there is a lack of recent evidence supporting efficacy and safety of molecule. The current study re-assessed the effectiveness and safety of isoxsuprine in managment of preterm labor in an Indian Multicenter setting.

## Materials & Methods

**N=170 Women with diagnosis of PTL** were treated at onset of PTL with an **intravenous infusion of Isoxsuprine hydrochloride followed by oral isoxsuprine therapy** (40 mg bd- daily) Assessment done at **12, 24 & 48 hours** of initiation of therapy & telephonic follow-up for delivery outcome.

**4 investigators from 4 centres across India participated in study.**

1. Dr. Shrinivas N Gadappa (Aurangabad) 3. Dr Arun Nayak (Mumbai)  
2. Dr Mary Snigdha (Nellore) 4. Dr Pragya Pandey (Varanasi)

**Primary Endpoint:** Percentage of women achieving Successful tocolysis at 24 and 48 hours after start of therapy

**Secondary Endpoints:** Percentage of women with (1) ADRs, (2) ADRs leading to discontinuation of isoxsuprine (3) Failure of tocolysis (4) Reduction in number of contractions at 12 hours

**Exploratory Endpoints:** (1) Percentage of women with healthy babies (2) Mean Birth Weight

## Results & Discussion

■ Successful tocolysis (165)

■ Tocolysis failure (5)

97%

3%

**99 patients (58%)**

achieved Reduction in uterine contractions after 12 hours of therapy

42%

58%

**Perinatal Outcomes**

**Mean Birth weight= 2.7 kg**

**Healthy babies =146(85.9%)**

**Successful tocolysis rate (97.1%)** indicate that isoxsuprine provided sufficient time for corticosteroids minimizing incidence of neonatal complications.

**ADR= 10 (5.9%)**

Lack of efficacy: 5 (2.9%)  
Fetal Distress: 2 (1.2%)

Still birth: 2(1.2%)  
Scar pain: 1(0.6%)

In response to AEs, **no action was taken with use of Isoxsuprine therapy. No clinically significant abnormality** like tachycardia or hypotension were reported

Isoxsuprine when used **in management of preterm labor resulted** in favorable outcomes in terms of birth weight and healthy babies (no congenital abnormalities)

**Conclusion:** Isoxsuprine was found to be an effective & well tolerated tocolytic agent in patients at risk of preterm delievery resulting in favorable maternal & perinatal outcomes

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**Abbreviations:** PTL: Preterm Labor; ADR: Adverse Drug Reaction; AE: Adverse Event

**Reference:** Data on File (Based on clinical study report) Effectiveness and Safety of Isoxsuprine Hydrochloride as Tocolytic Agent in Women with Preterm Labor in India—A Prospective, Open-Label Study.