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# Evaluating the safety and efficacy of antenatal corticosteroids in preterm labor: a randomized controlled trial

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**ABSTRACT**

Pre-birth corticosteroids (ACS) have been displayed to bring down mortality among early preterm youngsters in low-pay conditions, as per a WHO movement. I primer is at present the best controlled fundamental on ACS security and practicality. One of the most vital pre-birth drugs accessible to improve neonatal results is the utilization of corticosteroids before a commonplace preterm birth. For pregnant women between 24 0/7 weeks and 33 6/7 weeks of bring forth who are at risk for an extemporaneous work in something like 7 days, consolidating those with burst films and various difficulties, a single estimation of corticosteroids is proposed. Regardless of what the number of hatchlings or the condition of layer burst, it could in like manner be contemplated for pregnant women starting at 23 0/7 weeks of agonizing who are at risk for frightening work in the range of 7 days, dependent upon the family's decision concerning reclamation. Here, we review pieces of information acquired from the Action I primer that can be used with an impact helping ACS execution strategy. Significant components included (I) deciding gestational age by ultrasound, (ii) having qualified obstetricians utilize proper determination measures to recognize ladies in danger of preterm birth with the goal that ACS can be regulated, and (iii) offering a fundamental bundle of care to untimely babies in workplaces. This approach effectively diminished baby mortality from ACS utilization by 16% and distinguished a vital number of ladies who in the long run fell pregnant impulsively. To totally scale and weight the benefits of ACS in saving the presences of preterm children, policymakers, program bosses, and experts are asked to ponder this execution plan.

***Keywords:*** *Antenatal corticosteroids, preterm birth, clinical pharmacy services*

## 1. INTRODUCTION

The most widely recognized reason for child passings is preterm conveyance, which is characterized as conceiving an offspring before 37 weeks of pregnancy. Giving antenatal corticosteroids (ACS) to ladies who are in danger is one of the best pre-birth medicines to improve infant results when preterm birth is unavoidable [1]. Dependent generally upon early outcomes from high-resource nations, ACS has for some time been advanced as a fundamental arbiter to bring down preterm birth mortality and grimness. The delayed consequences of the huge people put together Antenatal Corticosteroids concentrate with respect to in low-and-canter compensation countries raised issues about the mediation's generalizability to low-asset conditions [2]. ACT, which was finished in six low-pay countries, showed that undertakings to propel the mother's use of ACS could have problematic effects. These results restored the conversation about the suitability and prosperity of ACS in low-pay nations, where contamination rates are higher and pre-birth care recommendations shift. A preterm birth is characterized by the World Wellbeing Association (WHO) as one that happens before 37 full, extensive long stretches of pregnancy or under 259 days following the beginning of a lady's latest feminine cycle. One An expected 14.84 million preterm infants are conceived every year, with 10.6% (95%CI 9.0-12.0) of all pregnant ladies considering a posterity before their due date. Over 80% of these preterm births happen in nations in South Asia and sub-Saharan Africa. Preterm conveyance entanglements are the main source of death for newborn children and youngsters under five, with an expected 1,000,000 passings annually.[3] Contrasted with term-considered kids, preterm infants are probably going to encounter various negative short-and long haul results, like learning handicaps, social issues, neurodevelopmental messes, and respiratory and other infant morbidities. For guardians and families, preterm birth and its delayed impacts can likewise have huge monetary and mental expenses. This prompts the third end throughout the entire existence of corticosteroids: clinical experts might turn out to be excessively anxious to utilize an intercession before there is adequate proof to help it. Giving rehashed portions of corticosteroids to pregnant ladies who were in danger of preterm conveyance quickly turned into the standard during the 1990s. As indicated by a 1995 survey, 96% of primatologists expressed that they should show many courses, and the larger

part guaranteed they would introduce no less than four repeating courses. [4] The NIH met one more comprehension gathering in 2000, just a short time after the get-together to help corticosteroid receipt, to determine the issue of repeated corticosteroid use, which had become so common. The board prescribed limiting rehashing gatherings of corticosteroids to patients associated with randomized clinical key assessments in light of the shortfall of data on the prosperity and sufficiency of this approach. It's furthermore beguiling to perceive how hasty decisions can soak standard clinical benefits establishments.

### *1.1 Impact of clinical Scenario in India*

Least consideration bundle for hopeful moms who risk giving conveyance too early. Each taking part organization had the option to analyse and securely treat preterm work and conveyance, as well as give suitable obstetric consideration. Every emergency clinic had the option to propose essentially the accompanying mediations: manual evacuation of held items, blood bonding, cesarean segment, hysterectomy, parenteral anti-microbials for peripartum contaminations, parenteral anticonvulsants for toxemia and eclampsia, and ultrasound assessments for gestational age (GA) appraisal with oxytocic drugs. [5] Before the examination started, the picked establishments in the five nations missing the mark on offices important to lead ultrasound tests for GA affirmation routinely. [4] The NIH met one more comprehension gathering in 2000, just a short time after the get-together to help corticosteroid receipt, to determine the issue of repeated corticosteroid use, which had become so common. The board prescribed limiting rehashing gatherings of corticosteroids to patients associated with randomized clinical key assessments in light of the shortfall of data on the prosperity and sufficiency of this approach. It's furthermore beguiling to perceive how hasty decisions can soak standard clinical benefits establishments. However, medical clinics were permitted to follow local procedures, even though this was unnecessary.

### *1.2 Outcomes, Risks, and Additional Considerations*

Research on various corticosteroid courses and animal data are the main sources of the worry that these drugs could negatively impact neurodevelopmental outcomes. According to the MFMU base on repeated course corticosteroids, something like four courses may be associated with the improvement of cerebral loss of movement. In any case, different tests have seen as no confirmation of long stretch hurt from a single course of corticosteroids managed at under 34 0/7 weeks of progress (truly, long stretch pneumonic has shown common determination and neurodevelopmental results, among various benefits). Directly following surveying five neurocognitive factors, there was no qualification in certifiable neurocognitive outcomes; in any case, a change to an antenatal corticosteroid treatment at term uncovered a differentiation in significant educator. [6] The Weschler scales, working memory and thought, and other neuropsychological tests didn't spread out a qualification there of brain across openness. Long stretch outcomes for the MFMU Antenatal Late Preterm Steroids starter are not yet open, but they would unimaginably expand the little game plan of data that is as of now available. Something else to remember with respect to the dangers of corticosteroids is that, even in instances of sepsis, pre-birth corticosteroids are not contraindicated in that maternal outlook.

## 2. RESEARCH OBJECTIVES

The inspiration driving the survey is to evaluate the advantages and expected risks of two ACS regimens when controlled to women with a high bet of preterm transport who are in the late preterm stage (gestational age of 34 weeks 0 days to 36 weeks 5 days): (I) 4 × 6 mg of dexamethasone phosphate predictably, or (ii) 4 × 2 mg of betamethasone phosphate as expected), as opposed to a phony treatment. The essential goal is to take a gander at the impact of each and every special ACS arm with a non-existent treatment on a composite consequence of stillbirth, infant youngster mortality, or use of breathing assist in something with loving 72 hours of birth or going before clinical focus conveyance, whichever begins things out. The optional goals are to assess the importance of each and every ACS methodology.

## 3. MATERIALS AND METHODS

From April 2008 to June 2010, we supervised a randomized, triple outwardly impeded, counterfeit treatment controlled clinical preliminary at the Establishment de Medicine Major Prof Fernando Figueira (IMIP), Recife, an enormous tertiary consideration clinical focus in northeastern Brazil. At the hour of facility affirmation, pregnant ladies who were 34-36+6 weeks along and in danger of a looming spontaneous work (either normally or in light of the fact that an early conveyance was prompted because of issues with the mother, incipient organism, or both) were remembered for the survey. To determine the woman's gestational age, either an ultrasound conducted before to week 20 of pregnancy or the date of her most recent period, if known and reliable, were used. Restriction from the survey depended on various elements, including various pregnancies, basic natural inconsistencies, haemorrhagic circumstances with current passing, clinical signs of chorioamnionitis, earlier utilization of corticosteroids, or the requirement for an early pregnancy end for either maternal or fetal reasons. After randomization, ladies who were let out of the facility while still pregnant and proceeded to imagine somewhere else were excluded from the survey.

### *3.1 Study population*

The model size was handled using open-source programming (Openepi structure 2.3, Atlanta, GA) with an ordinary 28.9%

speed of respiratory issues in late preterm newborn child young people, a α mess up of 5%, and a 80% ability to perceive a half decrease in the speed of respiratory issues with the utilization of corticosteroids. This provoked a basic model size of 266 (133 in every social event), which we extended to 320 to address excusals and mishap.

### *3.2 Antenatal Corticosteroids after Preterm Prelabour Rupture of Membranes at Different Gestational Ages*

Taking into account that newborn child mortality and orderliness are on the other hand associated with gestational age after entering the world, pre-birth corticosteroids may be generally invaluable at early gestational ages, yet their benefits could diminish at later gestational ages. Nevertheless, the upside of pre-birth corticosteroids at previable gestational ages has been tended to by virtue of the dull impediment of rebuilding of these adolescents in light of their much of the time low birthweight and very raw lung progress. In an organized assistant examination of 10,541 children brought into the world some place in the scope of 22 and 25 weeks of improvement, antenatal corticosteroids decreased the bet of death from neurodevelopmental impedance at 18 to 22 months of life.

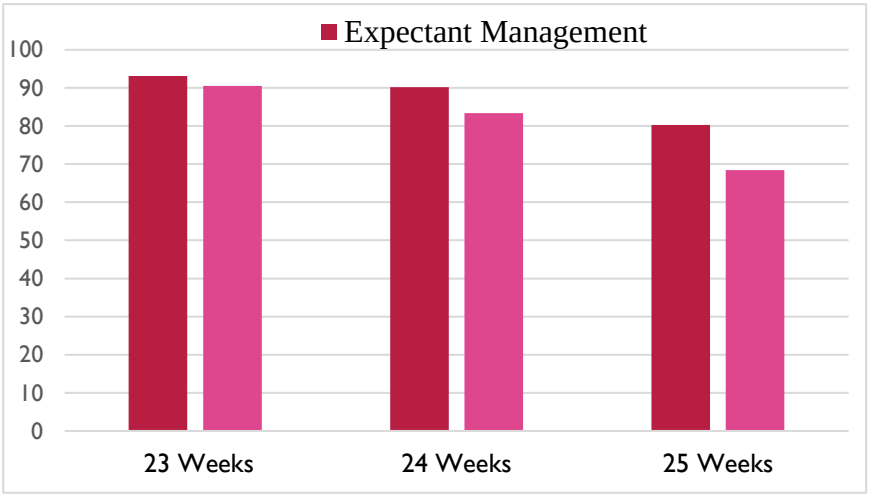


**Figure 1: Death and neurodevelopmental debilitation by antenatal corticosteroid openness among previable births.**

This reduction was striking for young people brought into the world at 23, 24, and 25 weeks agonizing when diverged from those conveyed at 22 weeks (Figure 1). Also, an assessment of most likely accumulated data on 11,022 newborn child kids brought into the world at 22 0/7 to 28 6/7 weeks of development revealed that antenatal corticosteroids diminished neonatal mortality at 23 to 27 weeks of incubating anyway didn't achieve certified importance among the subgroup of adolescents brought into the world at 22 weeks of development.13. Considering a more unassuming model size and lacking power, there was in all likelihood no effect seen among the subgroup of children brought into the world at 22 weeks, regardless of the way that ACOG doesn't as of now support considered pre-birth corticosteroid medication until 23 0/7 weeks of incubation.10, 11, and 14.

**Table 1: Demographic details of neonates**

| **Variables** | **Values (*N* = 405)** |
|---|---|
| **Age** (days)<br>Mean (SD) Median (IQR) | 16.12 (16.10)<br>10 (5-22) |
| **Gender** [*n* (%)] Boys<br>Girls | 245 (60.49)<br>160 (39.51) |
| **Gestational age** (weeks) [median (IQR)]<br>>37 (term) [*n* (%)]<br>33-37 (moderate to late preterm) [*n* (%)] 28-32 (very preterm) [*n* (%)]<br><28 (extremely preterm) [*n* (%)] | 36 (33-38)<br>273 (67.41)<br>80 (19.75)<br>46 (11.36)<br>6 (1.48) |
| **Birth weight** (g) [mean (SD)]<br>≥2500 (normal birth weight) [*n* (%)] 2499-1500 (low birth weight) [*n* (%)]<br>1499-1000 (very low birth weight) [*n* (%)]<br><1000 (extremely low birth weight) [*n* (%)] | 2503.39 (849.20)<br>226 (55.80)<br>120 (29.63)<br>49 (12.10)<br>10 (2.47) |
| **Birth weight percentiles** [*n* (%)] | 70 (17.28) |

| | |
|---|---|
| <10th (small for gestational age)<br>10th - 90th (appropriate for gestational age)<br>>90th (large for gestational age) | 330 (81.48)<br>5 (1.23) |
| **Length of NICU stay** (days) Mean (SD)<br>Median (IQR) | 10.59 (9.50)<br>8 (4-14) |

### *3.3 Statistical analysis*

Quantifiable assessment was finished using Espino programming variation 3.5.1 (Spots for Powerful expectation and Balance, Atlanta, GA) and the objective to treat rule. The analyser and the analysts didn't know anything about the treatment groupings until the tables were set up and the appraisal was done. The benchmark characteristics of each social occasion were investigated including the Mann-Whitney U test for discrete and ordinal factors or those with a non-typical scattering, and the Understudy's t test for determined components with an ordinary development. To think about clear factors, either Pearson's $\chi 2$ test or Fisher's unmistakable test were utilized, expecting to be material. All tests had two-followed P values, and the level of importance was set at 5%. The impact of corticosteroid drug on perinatal outcomes was overviewed using comparable tests. We handled risk extents as an extent of relative bet close by their 95% CIs to take a gander at respiratory and other newborn child issues considering whether corticosteroid or phony treatment was used. Resulting to adjusting to gestational age, we played out a Rack Haenszel isolated examination to become familiar with the bet of these issues. For the outcomes where we found a constructive outcome of corticosteroid treatment, the number expected to treat was enrolled alongside its 95% conviction range.

**Table 2. Reasons for NICU admission and medical conditions**

| **Variables** | ***n* (%), (*N* = 405)** |
|---|---|
| **Most common reasons for NICU admission** | 94 (23.21) |
| Tachypnea Jaundice Fever | 70 (17.28) |
| Prematurity care | 67 (16.54) |
| Further non-specified management Refusal to feed | 54 (13.33) |
| Grunting or excessive crying Abdominal distension | 21 (5.19) |
| | 10 (2.47) |
| | 5 (1.23) |
| | 5 (1.23) |
| **Number of sicknesses, [mean (SD)] Youngsters with one illness Children with two infections Youngsters with three illnesses** | 1.86 (0.92)<br>172 (42.47) |
| **Youngsters with four illnesses Children with five sicknesses** | 140 (34.57)<br>71 (17.53) |
| **ICD-10 characterization of diseases* Conditions starting in the perinatal period Irresistible and parasitic illnesses** | 455 (60.67)<br>127 (16.93) |
| **Inherent contortions, disfigurements irregularities Infections of the sensory system** | 40 (5.33) |
| **Illnesses of the respiratory framework Endocrine, wholesome and metabolic sicknesses** | 38 (5.07) |
| **Illnesses of the endlessly blood shaping organs Others#** | 31 (4.13) |
| | 18 (2.40) |
| | 14 (1.87) |
| | 27 (3.60) |

### *3.4 Identify Women Eligible for Acs Administration*

A ultrasound of adequate quality all through pregnancy affirmed that every woman considered equipped for the Action I fundamental had a GA between 26 weeks 0 days and 33 weeks 6 days. "Sufficient quality" suggested that a ultrasound uncovering fatal measures that considered a precise GA evaluation was driven by the canter sinology organization or a trustworthy ultrasound provider in another office or prosperity organization.

**Table 3: Eligible for Acs Administration**

| | | | | | |
|---|---|---|---|---|---|
| LMP is certain | Assuming contrast is ± 5 days, use LMP<br>In the event that distinction > 5 days, utilize U/S | On the off chance that distinction is ± 7 days, use LMP<br>On the off chance that distinction > 7 days, utilize U/S | Assuming distinction is ± 10 days, use LMP<br>If distinction > 10 days, utilize U/S | In the event that distinction is ± 14 days, use LMP<br>If distinction > 14 days, utilize U/S | Assuming distinction is ± 21 days, use LMP<br>If distinction > 21 days, utilize U/Sc |

If a dating ultrasound had not been performed during the woman's pregnancy or, in the opinion of the attending physician, was of an unsatisfactory quality, one was performed when she arrived at the preliminary clinic.

**Table 4: Predictors for hypertension during pregnancy**

| Characteristics* | Total (*N* = 1214) | Mothers with hypertension *(n = 146)* | Mothers without hypertension *(n = 1068)* | OR (95% CI); *P* Value |
|---|---|---|---|---|
| **Age** [*n* (%)] 14-18 | 12 (0.99) | 2 (16.67) | 10 (83.33) | 1.87 (0.40-8.75); 0.331 |
| 19-23 → | 622 (51.24) | 60 (9.65) | 562 (90.35) | Reference |
| 24-28 | 412 (33.94) | 44 (10.68) | 368 (89.32) | 1.12 (0.74-1.69); 0.599 |
| 29-33 | 110 (9.06) | 22 (20.00) | 88 (80.00) | 2.34 (1.37-4.01); 0.002 |
| 34-39 | 58 (4.78) | 18 (31.03) | 40 (68.97) | 4.22 (2.28-7.81); <0.001 |
| **Education** [*n* (%)] Illiterate Primary schooling# | | | | Reference |
| Secondary schooling | 22 (1.81) | 2 (9.09) | 20 (90.91) | |
| Pre-university University | | | | -- |
| (Not available)† | 12 (0.99) | 0 (0.00) | 12 (100.00) | 1.29 (0.29-5.68); 1.000 |
| | 438 (36.08) | 50 (11.42) | 388 (88.58) | 1.30 (0.30-5.72); 1.000 |
| | 452 (37.23) | 52 (11.50) | 400 (88.50) | 1.92 (0.43-8.55); 0.543 |
| | 224 (18.45) | 36 (16.07) | 188 (83.93) | -- |
| | 66 (5.44) | 6 (9.09) | 60 (90.91) | |
| **Occupation** [*n* (%)] Homemaker Employed | 1072 (88.30) | 114 (10.63) | 958 (89.37) | Reference |
| (Not available)† | 76 (6.26) | 24 (31.58) | 52 (68.42) | 3.88 (2.30-6.53); <0.001 |
| | 66 (5.44) | 8 (12.12) | 58 (87.88) | -- |
| **Consanguinity marriage** [*n* (%)] | 1034 (85.17) | 126 (12.19) | 908 (87.81) | Reference |
| None | 12 (0.99) | 0 (0.00) | 12 (100.00) | -- |
| First degree# Second degree | 90 (7.41) | 6 (6.67) | 84 (93.33) | 0.52 (0.22-1.20); 0.127 |
| Third degree (Not available)† | 72 (5.93) | 12 (16.67) | 60 (83.33) | 1.44 (0.76-2.75); 0.268 |
| | 6 (0.49) | 2 (33.33) | 4 (66.67) | -- |

As well as getting ultrasound gear, preliminary medical clinic representatives who performed obstetric ultrasounds got capability based, normalized preparing from proficient educators from the Worldwide Society of Ultrasound in Obstetrics and Genecology.

## 4. DISCUSSION

Most of standard boundaries didn't fundamentally vary across gatherings (table 2). 78% of the ladies in the two gatherings (111 in the mediation bunch and 101 in the fake treatment bunch) got the whole course of two dosages, and there was no way to see a contrast between the gatherings in such manner. In the two gatherings, the middle time between the last portion and conveyance was two days (interquartile range 1-4; P=0.49).

**Table 5: Baseline characteristics of pregnant women**

| Variables | Corticosteroid (n=143) | Placebo (n=130) |
|---|---|---|
| Mean (SD) age (years) | 23.3 (6.1) | 22.9 (5.5) |
| Middle (IQR) No of pregnancies | 1 (1-3) | 1.5 (1-3) |
| Primigravidas | 72 (50) | 65 (50) |
| Middle (IQR) No of conveyances | 0 (0-1) | 0 (0-1) |
| Nulliparas | 78 (55) | 69 (53) |
| Untimely break of layers | 54 (38) | 54 (42) |
| Untimely work | 97 (68) | 86 (66) |
| Diabetes | 3 (2) | 2 (2) |
| Fetal development limitation | 1 (0.7) | 2 (2) |
| Oligohydramnios | 15 (11) | 5 (4) |
| Others | 20 (14) | 12 (9) |
| Gotten tocolytics (nifedipine) | 88 (62) | 79 (61) |

Table 6 records the standard qualities of pregnant ladies between weeks 34 and 36 who are in danger of an approaching unexpected labor in light of whether they got corticosteroid or fake treatment medicine during pregnancy.

**Table 6: Prenatal outcomes for infants.**

| Variable | Corticosteroid (n=143) | Placebo (n=130) | Relative risk (95% CI) | P value |
|---|---|---|---|---|
| No (%) of vaginal conveyances | 98 (69) | 90 (69) | 0.99 (0.84 to 1.16) | 0.90 |
| Mean (SD) growth at conveyance (weeks) | 35.6 (1.17) | 35.5 (1.08) | — | 0.71 |
| No (%) <37 weeks' growth | 127 (89) | 119 (92) | 0.97 (0.90 to 1.05) | 0.45 |
| Mean (SD) birth weight (g) | 2640 (445) | 2627 (452) | — | 0.80 |
| No (%) <2500 g | 49 (34) | 51 (39) | 0.87 (0.64 to 1.19) | 0.40 |
| No (%) little for gestational age | 35 (25) | 29 (22) | 1.10 (0.71 to 1.69) | 0.67 |

Pre-birth results for babies conveyed between weeks 34 and 36 who are in danger of a looming impromptu work because of pre-birth corticosteroid medicine or plan are displayed in Table 3. The last assessment of a primer section was directed by joining ultrasound dating with a particular last regular ladylike period (LMP) (Box 2), utilizing the American School of Obstetricians and Gynaecologists calculation (Table 3).

**Table 7: Predictors for hypothyroidism during pregnancy**

| Characteristics* | Total (*N* = 1214) | Mothers with hypothyr oidism *(n = 100)* | Mothers without hypothyroidism *(n = 1114)* | OR (95% CI); *P* Value |
|---|---|---|---|---|
| **Age** [*n* (%)] → 14-18# 19-23 24-28 29-33 34-39 | 12 (0.99) 622 (51.24) 412 (33.94) 110 (9.06) 58 (4.78) | 0 (0.00) 34 (5.47) 50 (12.14) 10 (9.09) 6 (10.34) | 12 (100.00) 588 (94.53) 362 (87.86) 100 (90.91) 52 (89.66) | -- Reference 2.39 (1.52-3.77); <0.001 1.73 (0.83-3.61); 0.188 2.00 (0.80-4.97); 0.141 |
| **Education** [*n* (%)] Illiterate# Primary schooling# Secondary schooling Pre-university University (Not available)† | 22 (1.81) 12 (0.99) 438 (36.08) 452 (37.23) 224 (18.45) 66 (5.44) | 0 (0.00) 0 (0.00) 48 (10.96) 22 (4.87) 28 (12.50) 2 (3.03) | 22 (100.00) 12 (100.00) 390 (89.04) 430 (95.13) 196 (87.50) 64 (96.97) | -- -- Reference 0.42 (0.25-0.70); 0.001 1.16 (0.71-1.91); 0.607 -- |
| **Occupation** [*n* (%)] Homemaker Employed (Not available)† | 1072 (88.30) 76 (6.26) 66 (5.44) | 92 (8.58) 6 (7.89) 2 (3.03) | 980 (91.42) 70 (92.11) 64 (96.97) | Reference 0.91 (0.39-2.16); 1.000 -- |
| **Consanguinity marriage** [*n* (%)] None First degree Second degree Third degree (Not available)† | 1034 (85.17) 12 (0.99) 90 (7.41) 72 (5.93) 6 (0.49) | 84 (8.12) 4 (33.33) 6 (6.67) 4 (5.56) 2 (33.33) | 950 (91.88) 8 (66.67) 84 (93.33) 68 (94.44) 4 (66.67) | Reference 5.66 (1.67-19.17); 0.014 0.81 (0.34-1.91); 0.693 0.67 (0.24-1.87); 0.510 -- |

No unanticipated side effects or adverse reactions to corticosteroid therapy were seen, nor were there any neighbourhood or foundational secondary effects (data not displayed in tables). The perinatal results were comparable.

## 5. CONCLUSION

As of in the no so distant past, the unavoidable trust in the clinical treatment of high-risk pregnancies was that baby results

following 34 weeks of pregnancy wouldn't warrant essentially more thought. This has not been validated by ongoing investigations. It has been exhibited that late preterm babies experience clinically huge dismalness in spite of their low death rates, and an assessment of the information supporting current clinical practice is important. Remorsefully, our exploration demonstrates that corticosteroid medicine during pregnancy doesn't appear to bring down neonatal respiratory grimness essentially. Preterm birth is as yet a serious general medical problem regardless of whether the pace of preterm births in the US has at last begun to drop. One of the most essential obstetric treatments is the utilization of pre-birth corticosteroids to upgrade results following preterm birth. There are still concerns with respect to the accommodation of antenatal corticosteroids in unambiguous patient masses, as various turns of events, early preterm developments, and pregnancies tangled by intrauterine improvement constraint, in spite of the way that they have been exhibited to find actual success for singleton pregnancies in peril for preterm birth some place in the scope of 26-and 34-weeks advancement. Plus, the length of corticosteroid ampleness and the need of repeat or save segments stay obfuscated. Notwithstanding the significant amount of information that has been assembled on pre-birth corticosteroids throughout recent many years, more examination is as yet expected to work on the treatment's viability and results for these individuals who are in danger.

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