

Effectiveness of Castor Oil in Preventing Post-term Pregnancy in Low Resource Setting: A Randomized Controlled Trial

Okoro OS*, Ugwu EO, Dim CC, Ozumba BC, Nkwo PO, Ajah LO, Okeke TC

Department of Obstetrics and Gynecology, University of Nigeria Teaching Hospital (UNTH), Enugu, Nigeria

*Corresponding author: okoroonyemaechi@yahoo.com

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Abstract Castor oil has long been used as a way of inducing labor and preventing post-term pregnancy. However, its safety and effectiveness has not been conclusive thereby necessitating the need for further studies. This article evaluated the effectiveness of single oral dose of castor oil at 40-41 weeks of gestation for prevention of post-term pregnancy, in a low resource setting. This was a randomized controlled trial of pregnant women attending antenatal care clinic at the University of Nigeria Teaching Hospital Enugu, Nigeria. The eligible participants were randomized into two groups; group A (intervention group) received oral castor oil (60mls) and group B (control group) did not receive castor oil. The intervention group had a lower incidence of post term pregnancy compared to the control group (18/105(17.1%) vs 44/106(41.5%), RR= 0.41, NNT= 4). The proportion of women requiring formal induction of labor with misoprostol or with oxytocin was significantly lower in the intervention group than in the control group (18/105 (17.1%) vs 44/106(41.5%), RR= 0.41, NNT= 4). The intervention group were less likely to have their labor augmented with oxytocin compare to the control 41/87(47.1%) vs 44/62(71.0%), RR 0.66, NNT 4). The route of delivery and the need for new born special care unit admission were similar in the two groups. There was no significant difference in the maternal complications due to castor oil in the two groups. Single oral dose of Castor oil administration significantly lowers the incidence of post- term pregnancy, without higher risk of maternal and/ or neonatal complications.

Keywords: effectiveness, castor oil, preventing, post-term, pregnancy, Enugu, Nigeria

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1. Introduction

Post-term pregnancy complicates about 4-16% of pregnancies. [1,2] It is associated with increased risk of maternal and neonatal complications including increased risk of fetal macrosomia, induction of labor, caesarean section, shoulder dystocia, postpartum hemorrhage (PPH) amongst others. [1,3,4] In order to avoid these possible complications the best option would be to end the pregnancy before these complications occur.

One of the interventions for preventing post-term pregnancy includes oral administration of castor oil before 42 weeks gestation. Castor oil also known as oleum palmae Christi is obtained from the seed of *Ricinus communis*. [5] It is a triglyceride characterized by a high content of the hydroxylated unsaturated fatty acid ricinoleic acid. [6]

Currently, there are contradicting reports in the literature regarding the effectiveness and safety of castor oil for prevention of post-term pregnancy. Azhari and co-workers in a randomized controlled clinical trial

showed that there was a significant increase in labor ratio in those that received castor oil compared with the control. [7] They however recommended that further studies should be conducted to determine its efficacy and safety. In another study, Garry and co-workers demonstrated that a single dose of 60 mls of castor oil increases the incidence of active phase labor compared to control. It was concluded that women who received castor oil have an increased likelihood of initiation of labor within 24 hours compared to women who did not receive. [8]

In a study by Boel et al castor oil was not associated with any harmful effects on the mother or fetus but the time to birth was not significantly different between those who received castor oil and the control. [9] It was concluded that there was no justification for recommending castor oil for routine induction of labor. [9]

Currently, there is no safe method of induction of labor without maternal and fetal complications. The effectiveness of oxytocin and misoprostol in induction of labor has been well documented in the literature but they have potential maternal and fetal risks. [1] Their use requires patients' hospitalization and the attention of specially trained personnel for maternal and fetal

monitoring. Castor oil has been used by many people in preventing post-term pregnancy, and avoiding the need for formal methods of labor induction such as the use of oxytocin, misoprostol and artificial rupture of membranes. This may be due to its availability, affordability and may not require patient confinement to hospital bed for monitoring by trained personnel's as with other methods of formal induction. It is also anticipated to be less likely associated with the risk of hyper stimulation, hyper tonus, tachysystole, and uterine rupture, fetal or maternal death which are associated with most of the formal methods of induction of labor. However, the effectiveness of castor oil for prevention of post-term pregnancy is not certain which leaves a knowledge gap. This study was carried out to assert whether castor oil administration can be used as a routine prenatal care to prevent post-term pregnancy and possibly reduce the need for other costly methods of induction in our low resource setting.

2. Materials and Methods

The study was a randomized controlled study conducted at the Antenatal clinic/ labor ward of university of Nigeria teaching hospital (UNTH), Ituku/Ozalla, Enugu. The study participants were consenting women who attended the antenatal clinic of UNTH. The women were counseled on post-term pregnancy, and objectives of the study, following which, consent to participate in the study was sought and obtained. Eligible women were assigned by means of computer generated random numbers into 2 sample groups; group A (intervention group) received oral castor oil and group B (control group) did not receive castor oil. Exclusion criteria comprised women with Contraindications for vaginal delivery such as: (contracted pelvis, transverse lie, two previous caesarean section, placental praevia, Premature rupture of membranes, Bishop score of 5 and below (unfavorable cervix) at time of recruitment, post-date women that requested for membranes sweeping, as well as the women who, despite adequate counseling, declined to participate in the study

Those randomized to group A received single oral dose (60mls) of Bells B label castor oil (produced by Bell, sons LTD Southport England) at between 40-41 weeks gestation. The process began with initial cervical assessment for Bishop Score at the antenatal clinic. There were no membranes sweeping. Thereafter, they were given 60mls of oral castor oil to take in the clinic immediately after assessment. The time and date of ingestion of castor oil were noted. Her mobile phone number and contact address were recorded and was encouraged to call the investigator as soon as labor commenced and to immediately present to the labor ward for assessment and management of labor. At presentation at labor ward, the gestational age and the time of the onset of labor were documented.

For the purpose of this study, Castor oil was adjudged to have stimulated labor, if labor starts within 24 hours of the administration. [10]

Those randomized to non- administration of castor oil at 40 – 41 weeks (group B) had vaginal examination done to assess the initial Bishop score but did not take castor oil

and there was no membrane sweeping. The date and the time of assessment were noted. They were encouraged to call the investigator upon onset of labor and to present to labor ward for assessment and management. Their mobile phone numbers and contact address were also collected. The gestational age and the time of onset of labor were recorded.

When the participant went into active phase of labor, routine management of labor was adopted irrespective of the study group, using a partograph. Sonicaid was used to monitor the fetal heart rate intermittently. The uterine contractions, the vital signs of the mother and vaginal examination findings were recorded on a prescribed partograph.

The partograph was used to detect any occurrence of abnormality in labor and these abnormalities were treated with standard obstetrics intervention(s) as required for each situation. Those who fail to go into spontaneous labor in any arm of the study at 41 weeks and 3 days gestation were managed by formal method of induction (misoprostol and/or oxytocin) or caesarean section as the case may be by the managing unit.

The following information were recorded on a pro forma: hospital number, maternal age, gestational age, education status, marital status, parity and date/time of assessment, date/time of ingestion of castor oil and volume(for group A), the initial Bishop score, time of onset of regular contraction, time of assessment in labor ward, cervical dilatation on presentation, duration of active phase of labor, need for augmentation of labor, time of delivery, mode of delivery (vaginal, instrumental, caesarean section). Apgar score at first and fifth minutes and birth weight were noted at delivery, total duration of labor, and Side effects reported by the mother (nausea, vomiting, diarrhea, abdominal pain, shivering, fever, tachysystole, hyper stimulation, uterine rupture, post partum hemorrhage and laceration) and the need for new born special unit admission.

The sample size for each group was determined as $n= 97$ (minimum sample size in each group) (Kirkwood 1988). [11] Assuming an attrition rate of 10% for possible drop outs or loses to follow up; the minimum sample size in each group was 106, corresponding to 80% statistical power and 5% level of significance. Data was analyzed with Statistical Package for Social Sciences version 20 software (IBM SPSS Inc., Chicago, IL, USA). Categorical variables were analyzed using McNemar's test and Pearson Chi-squared test. The level of significance was set at ≤ 0.05 . The ethical clearance for this study was obtained from the Health Research Ethics Committee of UNTH.

3. Results

A total of 216 women out of 235 women with post date pregnancies during the period of the study met the eligibility criteria and gave their consent to participate in the study. The 216 women enrolled for the study were randomized equally into Castor oil administration group ($n= 108$) and control group ($n= 108$). Five women did not give birth in our hospital and were lost to follow up. Two hundred and eleven women completed the study and were

analyzed comprising 105 participants in the study group and 106 in the control group, as shown in flow chat (Figure 1).

As shown in Table 1, there was no significant difference between the two groups regarding their socio-demographic characteristic.

Participants who received castor oil had a lower incidence of post term pregnancy compared to the control group {18/105 (17.1%) vs 44/106 (41.5%), RR 0.41, NNT 4}. Eighty seven women 87/105(82.9%) in the castor oil administration group delivered before post-term while 62/106 (58.5%) in the control group delivered before post-term (RR 1.43, NNT 4) as shown in Table 2.

Further analysis showed that women who received castor oil were also significantly more likely to deliver within 48 hours from the time of recruitment (intervention) than the control group {51/105(48.6%) vs 23/106(21.7%); RR 2.23, NNT 3.7}. The incidence of post-term pregnancy in the intervention group was 24.4% less than that of the control (relative risk reduction) and the result also showed that only four women needed to receive castor oil in order to prevent a case of post-term pregnancy (number needed to treat). The proportion of women requiring formal induction of labor (using misoprostol and or oxytocin) after castor oil administration was significantly lower in the intervention group than in the control group {18/105 (17.1%) vs 44/106 (58.5%), RR 0.41, NNT 4} details as shown in Table 3.

Women who received castor oil were significantly less likely to have their labor augmented with oxytocin compare to the control {41/87(47.1%) vs 44/62(71.0%), RR 0.66, NNT 4} details as shown in Table 4.

Women in the Castor oil administration group were significantly more likely to go into labor within 24 hours from the time of recruitment (intervention) than the control group {60/105 (57.1%) vs. 4/106 (3.80%); RR=14.25, NNT 2}. Details of recruitment to onset of labor as shown in Table 5.

However, the mean duration of the active phase (in hours) did not differ between the two groups {10.9 ± 5.2 vs 10.8 ± 2.3; P = 0.93}.

The route of delivery was similar between the two groups (Table 6). The labor complications were also similar in the two groups and were mainly 'presumed' fetal distress, prolonged labor, maternal exhaustion and prolonged second stage labor.

The caesarean section rate was similar in the two groups as shown in Table 6.

The neonatal outcome including the 1st and 5th minute APGAR scores, birth weight and the need for admission into NBSCU was similar between the two groups (Table 7).

There was no significant difference in the maternal complications due to castor oil in the two groups. There was no case of clinical chorioamnionitis, hyper stimulation, uterine rupture and meconium stained liquor in the two groups. Details as shown in Table 8.

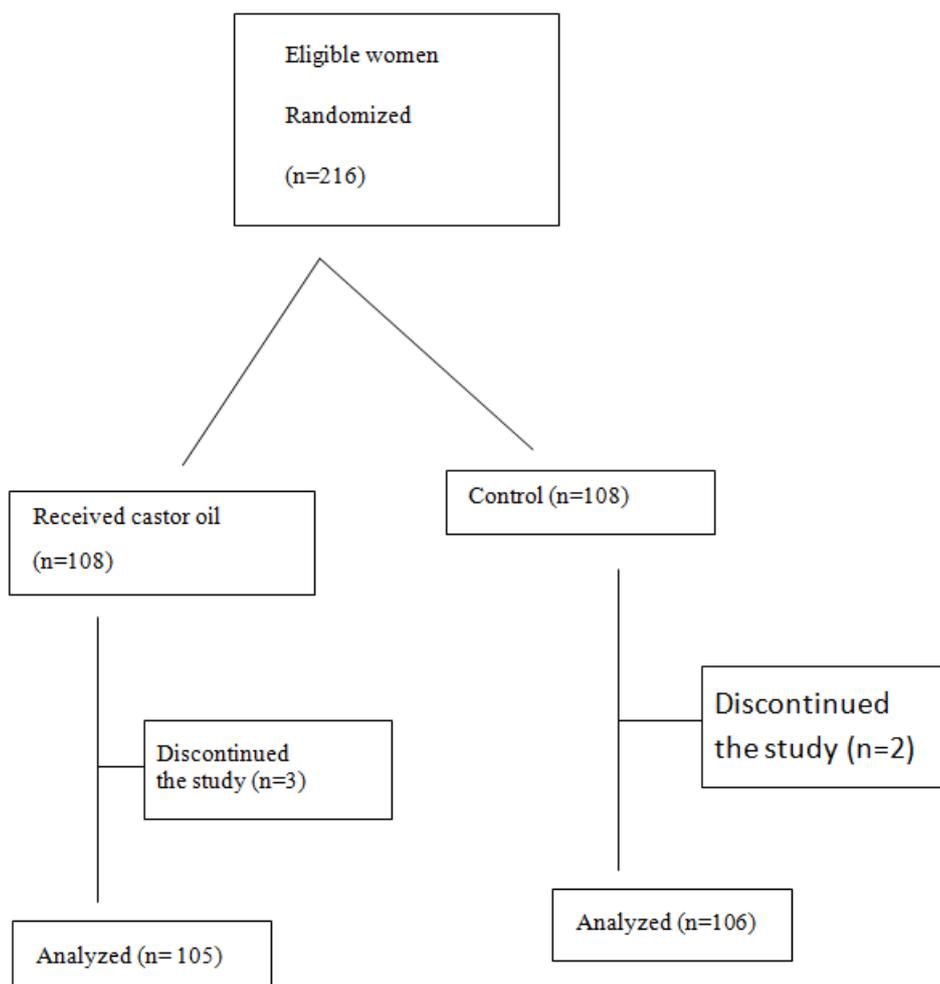


Figure 1. Flow Chart of the Study

Table 1. BASELINE CHARACTERISTICS OF THE PARTICIPANTS*

	Castor oil administration n=105	Control n=106	P-value
Age(years) mean± SD	28.7±3.9	28.2±3.1	0.09
Parity			
Nulliparous (%)	44 (41.9)	47(44.3)	0.09
Multiparous (%)	50 (47.6)	49 (46.2)	0.27
Grandmultiparous (%)	11(10.5)	10(9.5)	0.20
Gestational age (wks) mean± SD	40 ⁺³ ±2.1	40 ⁺⁴ ±2.4	0.50
Pre-recruitment Bishop score			
6-9(%)	67(63.8)	66(62.3)	0.58
10-13(%)	38(36.2)	40(37.7)	0.58
Previous post-dates (>40wks)(%)	26(24.8)	27(25.5)	0.84
Previous labor induction (%)	12(11.4)	11(10.4)	0.79

Table 2. THE EFFECT OF ADMINISTRATION OF CASTOR OIL ON THE INCIDENCE OF POST TERM PREGNANCY

	CASTOR OIL GROUP N= 105 (%)	CONTROL N= 106 (%)	RR	NNT
PROPORTION OF WOMEN THAT PROGRESSED TO POST TERM	18(17.1)	44(41.5)	0.41	4
PROPORTION THAT DELIVERED WITHIN 48 HOURS OF RECRUITMENT	51(48.6)	23(21.7)	2.23	3.7

Table 3. THE NEED FOR FORMAL INDUCTION OF LABOR AFTER ADMINISTRATION OF CASTOR OIL

	Castor oil group n=105 (%)	Control n=106 (%)	RR	NNT
Proportion of women that required induction	18 (17.1)	44(41.5)	0.41	4

X² for categorical variables

Note that the 87 women and the 62 women that delivered in the castor oil group and control group respectively were excluded.

Table 4. ADMINISTRATION OF CASTOR OIL ADMINISTRATION AND THE NEED FOR AUGMENTATION OF LABOR

	Castor oil group n= 87 (%)	Control group n= 62 (%)	RR	NNT
Proportion of women that had their labor augmented with oxytocin	41(47.1)	44(71.0)	0.66	4
Mean duration of active phase of labor(in hours) mean± SD	10.9 ± 5.2	10.8 ± 2.3		Not available

Table 5. EFFECT OF CASTOR OIL ADMINISTRATION ON ONSET OF LABOR WITHIN 24HOURS

	Castor oil group n=105 (%)	Control n=106 (%)	RR	NNT
First 24 hours	60(57.1)	4 (3.8)	14.25	1.9
>24 hours	45(42.9)	102 (95.8)	0.45	1.9

X² for categorical variable.

Table 6. THE EFFECT OF CASTOR OIL ADMINISTRATION AND THE ROUTE OF DELIVERY

Route of delivery	Castor oil group n=87 (%)	Control n=62 (%)	P value
Vaginal	75(86.1)	45(72.6)	
Spontaneous	69(92.0)	37(82.2)	
Assisted (vacuum)	6(8.0)	8(17.8)	0.19
Indications for assisted delivery:			0.10
Fetal distress	3(50.0)	5(57.1)	0.48
Maternal exhaustion	0	1(14.3)	
Prolonged 2 nd stage	3(50.0)	2(28.6)	
Caesarean section	12(13.9)	17(27.4)	
Indications for C/S:			0.19
Fetal distress	1(9.1)	3(20.0)	
Prolonged labor	11(90.9)	14(80.0)	

X² test

NB: Women (castor oil group 18, and control 44) whose pregnancies progressed to 41weeks and 3days were excluded.

Table 7. THE NEONATAL OUTCOME AND CASTOR OIL ADMINISTRATION

	Castor oil group n=87 (%)	Control n=62 (%)	P value
Birth weight (Kg)			
<2.5	3(3.8)	2(3.3)	
2.5-4.0	75(86.2)	50(80.6)	0.81
>4.0	9(10.3)	10(16.1)	
1 st min APGAR score			
<7	15(17.8)	7(11.3)	
≥ 7	72(82.2)	55(88.7)	0.10
5 min APGAR score			
<7	12(13.9)	9(14.3)	
≥	75(86.1)	53(85.7)	0.54
Admission to NBSCU	7(8.0)	5(8.9)	0.66

Table 8. MATERNAL COMPLICATIONS FOLLOWING CASTOR OIL ADMINISTRATION

	Castor oil group n= 105 (%)	Control n= 106 (%)	P value
Clinical chorioamnionitis	0	0	0
Prelabor rupture of membranes	9(8.6)	10(9.4)	0.67
Hyper stimulation	0	0	0
Abdominal pain	0	0	0
Vomiting	4(3.8)	2(2.1)	0.45
Diarrhea	3(2.9)	1(1.2)	0.48
Uterine rupture	0	0	0
Meconium stained liquor	0	0	0

4. Discussion

The basic characteristics of the participants in this study such as the age, parity, pre recruitment Bishop Score, previous post dates as well as previous labor induction did not differ significantly between the castor oil and control group. This is in agreement with reports from previous related studies. [7,8,9,12,13]

The study demonstrated that castor oil administration can prevent post-term pregnancy, as the incidence of post-term pregnancy was significantly lower in the castor oil group (17.1%) compared to the control group (41.5%) with relative risk of 0.41. The incidence of post-term pregnancy in the intervention group was thus 24.4% less than that of the women that did not receive castor oil (relative risk reduction). Interestingly, this showed that only four women needed to receive castor oil in order to prevent a case of post-term pregnancy (number needed to treat). This agrees with the reports of previous related studies from other centers. [8,14] Garry and co-workers in a prospective case control study of 103 pregnant women showed that women who received castor oil have an increased likelihood of initiation of labor within 24 hours compared to women who receive no treatment, it also noted that when castor oil is successful, 83.3% of the women delivered vaginally and that castor oil use in pregnancy is under reported worldwide. [8] Mathie and Davison in their study demonstrated that castor oil is capable of initiating labor near term and can prevent post-term pregnancy. [14] However, Boel et al in a retrospective study documented that the time of birth was not significantly different between those who received castor oil and the control. [9] Considerable heterogeneity in these studies in terms of the methodological design/approach might be responsible for the differences in the results obtained. The present study evaluated the effectiveness of castor oil in a subgroup of term pregnant women with ripe cervix, whose pregnancies have progressed to the expected date of delivery (EDD) and beyond but not yet to post-term. It is highly probable that this subgroup of term pregnant women may have better respond to castor oil than women below their EDD since the effect of castor oil increases with gestational age. [8] This may have contributed to the significant favorable outcome obtained in this study.

Result from this study demonstrated that castor oil administration between 40-41 week gestations reduces the need for formal induction of labor with misoprostol or oxytocin. This is in agreement with Azhari and co workers that documented a significant rise in mean Bishop score and increase labor ratio following castor oil administration. [3]

The need for hospital confinement and monitoring by hospital staff for those that need formal induction of labor can to a large extent be obviated through castor oil administration. Castor oil administration is thus very useful in a low resource setting like ours where payments for maternal and neonatal health care services are often out of pocket and where many women have aversion for formal induction of labor and or caesarean section.

The significant reduction in the need for oxytocin augmentation as shown in this study may imply that the extra cost of oxytocin augmentation and the possible complications as well as intense monitoring associated with oxytocin augmentation will be avoided.

The result of this study suggests that women who received Castor oil were significantly more likely to go into labor within 24 hours from the time of recruitment (intervention) than the control group. This is in agreement with report of related studies from other centres^{7,8} Azhari and co-workers in a randomized controlled clinical trial of 47 pregnant women showed that there was a significant increase in labor ratio in those that received 60 mls of castor oil compared with the control (54.2% compared with 4.3%), it equally noted a significant rise in the mean Bishop score in the castor oil group compared to the control after 24 hours. [7] In another study, Garry and co-workers in a prospective case control study of 103 pregnant women demonstrated that 30 out of 52 (57.7%) women that received single dose of 60 mls of castor oil began active phase labor compared to 2 of 48 (4.2%) women receiving no treatment within 24 hours. [8] Castor oil administration is thus capable of not only initiating labor within 24hours of intervention but significantly guaranteed delivery within the same period implying that it is an effective method to be considered whenever labor/delivery is strongly desired between 40-41 weeks gestation.

This study showed that the route of delivery was similar between the participants in the two groups and the caesarean section rate was similar in the two groups. The labor complications were also similar in the two groups and were mainly 'presumed' fetal distress, prolonged labor, maternal exhaustion and prolonged second stage labor. This is in keeping with the result of related previous study. [8] The clinical implication is that administration of castor oil did not seem to increase the rate of caesarean section as well as labor complications and this is important in our setting where women have aversion for caesarean section.

The neonatal outcome including the 1st and 5th minute APGAR scores, birth weight and the need for admission into NBSCU was similar between the two groups. This finding suggests that castor oil did not seem to have

harmful effect on the fetus. This is in agreement with Boel et al that documented that castor oil was not associated with any harmful effects on the fetus. [9]

The fear of increased risk of meconium stained liquor by previous study was not evident in this study as no case of meconium stained liquor was demonstrable in this study. Thus, castor oil administration did not seem to predispose the babies of the recipients to the adverse effects of meconium stained liquor, this finding is in agreement with that noted by Davis in his study. [13] Davis in a related study reported a higher rate of labor initiation in a group of pregnant women that received castor oil compared to the control (75% versus 58%) but did not observe any increase in the rate of meconium stained liquor in the castor oil group when compared to those who did not receive treatment, [6] this finding contrasts the report of Mitri and co-workers which showed an increase in the rate of meconium stained liquor in the castor oil group. [8]

The result of this study demonstrated that there was no significant difference in the maternal complications in the two groups. Though women who received castor oil had higher incidence of vomiting and diarrhea but these were not statistically significant. There was no case of clinical chorioamnionitis, hyper stimulation, or uterine rupture in the two groups. This finding suggests that castor oil did not seem to have any adverse or harmful effect on the mother in agreement with findings from previous related study. [9] In a retrospective study of 612 pregnant women, Boel et al documented that castor oil was not associated with any harmful effect on the mother or fetus. [9]

The overall clinical implication of this favorable outcome is that castor oil administration when judiciously employed is capable of preventing the progression of pregnancies to post-term amongst women whose pregnancies have progressed to/or beyond the estimated date of delivery without any obvious increase in maternal or fetal complications. It also reduces the need for augmentation of labor/formal induction of labor, thereby reducing the extra cost, monitoring and possible complications associate with it. Even though that this study was a randomized controlled study, there were some limitations. The minimum sample size as used in this study was not large enough to study for the rare adverse effects of castor oil. Again, in this study only single oral dose of castor oil was used, it is suggested that use of repeated doses of castor oil could improve the outcome.

5. Conclusion/recommendation

Single oral dose of Castor oil administration significantly lowers the incidence of post- term pregnancy, without higher risk of maternal and/ or neonatal complications.

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Statement of Competing Interest

There was none.

Abbreviations

RR= relative risk,
NNT= number needed to treat)
NBSCU= New born special care unit.

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