

PPROMT - Immediate Delivery versus Expectant Care in Women with Preterm Prelabour Rupture Of the Membranes close to Term (PPROMT) – a Randomised Controlled Trial.

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BACKGROUND

Preterm prelabour rupture of membranes complicates up to 2% of all pregnancies and is the cause of 40% of all preterm births. Best practice for those women who rupture their membranes *preterm*, that is, prior to 37 weeks, is not known. Clinical decision-making requires consideration of the potential risks and benefits of planned elective delivery against expectant management until term, or until complications such as chorioamnionitis intervene, necessitating delivery. In a survey conducted of the RANZCOG membership, it was demonstrated that there was clinical equipoise with regard to current management of PPRM.

AIM

The aim of the study is to answer the question, in women between 34 and 36⁶ weeks gestation, with confirmed ruptured membranes, is immediate delivery compared with expectant management associated with:

1. Less neonatal and maternal morbidity compared with expectant management
2. Fewer economic costs compared with expectant management

METHODS

The PPRMOT Trial is a large, multi-centre, international, randomised controlled trial, with stratification for centre and gestational age. It is funded by an NHMRC grant and is coordinated from the Royal North Shore Hospital, Sydney. The enrolment goal is 1812 women (906/group) over a four-year period from 2005 – 2009. The sample size is designed to detect a 50% reduction in neonatal sepsis from 5% in the expectant arm to 2.5% in those managed with planned early delivery.

The primary study endpoint is the incidence of neonatal sepsis, classified as either definite or probable by an adjudication committee blinded to treatment allocation. Secondary maternal and infant endpoints including outcomes include measures such as chorioamnionitis and respiratory distress. Early infant development and maternal satisfaction are measured by questionnaires at four months post-partum.

If it is established that long-term maternal and child outcomes are likely to be equivalent between the treatment groups, a cost analysis will be conducted.

RESULTS

With 50 centres in 7 countries participating, we are still seeking more centres to become involved with the trial to reach the recruitment rate in the given time.

CONCLUSIONS

This trial will provide the highest level evidence to date in order to determine whether immediate delivery of women with preterm prelabour rupture of the membranes is associated with less neonatal and maternal morbidity, and fewer economic costs, when compared with expectant management.