

AVAILABLE MFMU DATE SETS

BEAM Trial: Randomized Clinical Trial of the Beneficial Effects of Antenatal Magnesium

Objective: To test the hypothesis that prophylactic magnesium sulfate at 24-31 weeks gestation for whom delivery is imminent (with advanced preterm labor, with pPROM, or for whom delivery is less than 24 hours), reduces the risk of mortality and moderate to severe cerebral palsy at 2 years of age in their children.

Conclusion: MgSO₄ may afford the fetus destined to be born preterm substantial protection against cerebral palsy, without increasing the risk of stillbirth or infant death.

CAPPS: Combined Antioxidants and Preeclampsia Prediction Studies

Objective: To determine whether antioxidants reduce the frequency of serious maternal and infant complications associated with pregnancy related hypertension.

Conclusion: Therapy initiated with the antioxidant Vitamins C and E prior to 17 weeks gestation in nulliparous low risk women does not reduce the frequency of complications associated with pregnancy related hypertension, nor does this treatment reduce the diagnosis of preeclampsia.

Cervical Ultrasound Study: Mid-Trimester Endovaginal Sonography in Women at High Risk for Spontaneous Preterm Delivery

Objective: To test the hypothesis that mid-trimester endovaginal sonography can identify a group of high risk women whose cervical characteristics define them as candidates for a future clinical trial of cerclage or other intervention strategies.

Conclusion: Cervical length at 16-18 weeks of gestation predicts spontaneous preterm delivery < 35 weeks in women with a prior early spontaneous delivery. Information derived from serial scans is associated with higher relative risk and sensitivity. These data will be useful in designing future intervention trials.

Cesarean Section Registry: An Observational Study of Cesarean Section and Vaginal Birth After Cesarean Section

Objective

1. To determine the patient characteristics of women undergoing a trial of labor (TOL) and to determine the efficacy and safety of trial of labor.
2. To determine the cesarean delivery rates, indications for operative intervention, intrapartum patient management and outcome by payer and provider status.
3. To estimate the frequency of maternal and neonatal complications of cesarean delivery.
4. To determine factors influencing maternal and neonatal outcome in women undergoing cesarean delivery.

Conclusion: To be determined

Factor V Leiden: A Prospective Observational Study of Effects of Factor V Leiden Mutation on Maternal and Perinatal Outcome

Objective: To determine the incidence of pregnancy-related thromboembolism in women carrying the Factor V Leiden mutation.

Conclusion: Among women with no history of prior thromboembolic events, maternal heterozygous carriage of the FVL mutation is associated with a low risk of pregnancy-related venous thromboembolism. Neither universal prenatal screening for the FVL mutation, nor treatment of the low-risk carrier during pregnancy is indicated. Treatment of the low-risk carrier during pregnancy is indicated.

HRA(High Risk Aspirin): Clinical Trial of Low-Dose Aspirin To Prevent Preeclampsia in High Risk Women

LRA (Low Risk Aspirin): Randomized Trial of Low-Dose Aspirin to Prevent Preeclampsia

Objective: To establish whether daily administration of low-dose (60 mg) aspirin to nulliparous obstetrical patients will decrease the incidence of preeclampsia.

Conclusion: The trial concluded that low-dose aspirin marginally decreased the incidence of preeclampsia among nulliparous women (4.6% vs 6.3%, p=0.05), but increased the risk of abruptio placentae and did not improve overall perinatal morbidity.

ODNS: MFMU Network Registry of Obstetrical Determinants of Neonatal Survival

Objective: To examine the effectiveness of using obstetrical prognostic factors to predict the survival of infants born weighing 1,000 grams or less.

Conclusion: The approach to obstetric management significantly influences the outcome of extremely low-birth-weight infants. Above 800 gm or 26 weeks, the OB should usually be willing to perform cesarean delivery for fetal indications. Between 22 and 25 weeks willingness to intervene results in greater likelihood of both intact survival with serious morbidity. In these cases patients and physicians should be aware of the impact of the approach to OB management and consider the likelihood of serious morbidity and mortality when formulating plans for delivery.

Progesterone Trial: Randomized Clinical Trial of 17 alpha-Hydroxyprogesterone Caproate for Prevention of Preterm Birth in High Risk Women

Objective: To test the hypothesis that administration of 17 alpha-hydroxyprogesterone caproate initiated before 21 weeks gestation will reduce the risk of preterm birth in women who have previously experienced an early spontaneous preterm delivery.

Conclusion: Weekly injections of 17 alpha-hydroxyprogesterone caproate resulted in a substantial reduction in the rate of recurrent preterm delivery.

Progesterone Follow-up: A Follow-Up Study of the Children in the Progesterone Trial

Objective: To determine whether there is a difference in achievement of developmental milestones and physical health between children whose mothers received progesterone and those who received placebo in a previous MFMU Network trial.

Conclusion: To be determined

Steroids Trial: A Randomized Placebo-Controlled Clinical Trial of Antenatal Corticosteroid Regimens

Objective: To test the hypothesis that in women < 32 weeks gestation who are at risk for spontaneous preterm delivery and who remain pregnant more than with seven days after initial corticosteroid therapy, weekly re-administration of corticosteroids will decrease neonatal morbidity compared with a single course of corticosteroids.

Conclusion: Repeated exposure to antenatal corticosteroids significantly reduced specific neonatal morbidities but did not improve composite neonatal outcome. This was accompanied by a reduction in birth weight and an increase in small for gestational age infants.

STTARS: A Randomized Study of Seventeen Alpha-Hydroxyprogesterone Caproate in Twins and Triplets

Objective: To determine whether 17 Alpha-Hydroxyprogesterone prevents preterm birth in multifetal pregnancies.

Conclusion: Treatment with 17 Alpha-Hydroxyprogesterone caproate did not reduce the rate of preterm birth in women with multigestations.