INTERNATIONAL MULTICENTRE RCT OF AMNIOINFUSION

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Sponsors:
UTAH Medical
Steering Committee

- A serious and frequent neonatal condition associated with meconium staining of the amniotic fluid.
- 2.0% to 18% of infants delivered through MSAF develop MAS

Primary objective
To determine if a policy of amnioinfusion
(AI) for thick MSAF prevents :

- Perinatal death
- Moderate to severe Meconium Aspiration Syndrome

Secondary objectives

- To assess the effects of AI on composite indicators of neonatal and maternal morbidity

Inclusion criteria

- Singleton pregnancy, GA >36 weeks
- Established labor, cephalic presentation
- Thick meconium,
- Cervical dilatation : 2 and 7 cm
- Fetal status acceptable on > 30 minute EFM tracing
- Consent documented on IRB approved form

Exclusion criteria

- Major fetal anomaly
- Chorioamnionitis
- Placenta praevia or recent vaginal bleeding
- Known or suspected HIV, hepatitis B or C
- Uterine overdistension
- Previous uterine incision other than low transverse

Randomization

- Centralized
- Computerised
- Stratified by centre
- Stratified by:
  Stratum I: less than 3 variable decelerations
  Stratum II: ≥ 3 variable decelerations

Characteristics of AI fluid

- Sterile room temperature saline
- Bolus: 800 ml 2 ml/min X 40 min
- Infusion continued at 2 ml/min
- Maximum : 1500 ml

Meconium Aspiration Syndrome

- Respiratory distress, first 4 hrs requiring O_2
- Moderate MAS
- FIO2 ≥ 40% or ≥48 hours
- Severe MAS
- Requiring mechanical ventilation

Blindly adjudicated by 3 neonatologists
Composite serious neonatal morbidity
Composite Serious maternal morbidity

- Uterine rupture
- Antepartum hemorrhage
- Hysterectomy
- ICU admission
- Maternal Death
- Disseminated intravascular coagulation
- Postpartum hemorrhage with transfusion

Statistical analysis

Analysis by intention to treat

- Sample size : 982 per group
- Expected Primary outcome, Control - 6%
- Expected effect size - 0.5
- Power 0.85 Alpha 0.05

- Two interim analyses by DSMC.
  They advised continuation of trial.

RESULTS
Patient recruitment by country: 56 centres, 13 countries
Treatment groups similar with respect to baseline variables:

- Maternal age
- Parity
- Maternal Education
- Gestational Age
- BMI
- Oxytocin use

Proportion of AI performed in two groups
Primary outcome

Secondary Morbidity indicators
Stratified analysis

Conclusion:
■In women with thick meconium staining of the AF, amnioinfusion is NOT effective in preventing:
–MAS
–other serious neonatal morbidity.

■Amnioinfusion does NOT decrease the risk of cesarean section in this population.
Conclusion:
■A planned secondary analysis of perinatal and maternal effects by stratum - (presence or absence of variable decels) :

–No evidence of heterogeneity of effects accross strata.

Discussion

■Stratified analysis: primary
■Stratum - cesarean
■MAS with Abn CXR
■Fetal HRT – Stratum
■Cx dilatation and durlab

■Stratified by Hemisphere: Primary
■Complications
■Technique
■Fetal assessment
■Recusscitation
■Baseline characteristics

Neonatal outcomes Stratified
Caesarean delivery rate by stratum
Primary Outcome by Hemisphere

Abnormal FHR tracing requiring
clinical intervention by stratum

Labour characteristics
Complication during AI

Description of study intervention
Co-interventions :
fetal assessment
Baseline Maternal Characteristics [1]
Baseline charcterisitics of mother and baby