

diabetes, prior bariatric surgery, and IVF. The intervention included an individualized dietitian-prescribed calorie-specific DASH-type diet, physical activity, internet-based self-monitoring of diet adherence, and weekly coaching calls, with opportunities for group visits, webinars, and podcasts. Usual care participants were provided websites, electronic newsletters, and non-diet related pregnancy information. Obstetric providers and data collectors were not aware of patient group assignment.

**RESULTS:** 281 participants were randomized to the intervention or usual care, with complete data available for all but 2 patients. Baseline characteristics of maternal age, parity, gestational age at randomization, race, ethnicity, and pre-pregnancy BMI were similar. There were 4 pregnancy losses after randomization but before 24 weeks (data not included), and 1 fetal death after 24 weeks. The intervention group gained significantly less weight from enrollment to 36 weeks than the usual care group, and fewer participants exceeded the IOM recommendations (table). This did not result in fewer diagnoses of gestational diabetes, preeclampsia or gestational hypertension, or birth weight >4 kg; a higher rate of cesarean birth was observed in the intervention group.

**CONCLUSION:** The MOMFIT behaviorally adapted, nutrient-dense, energy-balanced diet and lifestyle intervention resulted in better adherence to IOM guidelines for gestational weight gain, but improvements in pregnancy outcomes were not observed.

Outcome	Intervention (n=139)	Usual care (n=135)	p-value
Overall GWG (lbs, enrollment to 36wk)*	19.1 ± 10.3	23.7 ± 10.2	<.001
Overall GWG (lbs, self-reported prepreg to 36wk)*	22.5 ± 12.3	25.3 ± 21.4	0.20
Rate of weight gain (lbs/wk)	0.9 ± 0.5	1.1 ± 0.5	<.001
Participants exceeding 2009 IOM guidelines **	95 (68%)	116 (86%)	<.001
Gestational age at delivery	39.2 ± 1.8	38.9 ± 1.9	0.12
Gestational diabetes	9 (6%)	11 (8%)	0.59
Preeclampsia or gestational HTN	12 (9%)	14 (10%)	0.62
Cesarean delivery	55 (40%)	36 (27%)	0.023
Birth weight (gm, mean ± SD)	3422 ± 545	3367 ± 616	0.43
Birth weight >4000 gm	17 (12%)	17 (13%)	0.93

\*excluding patients delivering before 36 weeks; \*\* >0.7 lbs/week if overweight; >0.6 lbs/week if obese

### 3 Routine antenatal ultrasound in low/middle income countries: a cluster randomized trial



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**OBJECTIVE:** US is commonly used at antenatal care (ANC) in high-income countries (HIC) despite little evidence that it reduces maternal, fetal or neonatal mortality. In LMIC, US may increase ANC use and referrals for complications. We tested the hypothesis that US-naïve providers could be trained to perform basic obstetric US and using these providers whether ANC and referrals would increase and result in improved outcomes.

**STUDY DESIGN:** This intent-to-treat trial of 46,838 women and nearly 50,000 exams was performed in 58 clusters (geographic areas of ≥350 births/year) in Pakistan, Kenya, Zambia, DRC and Guatemala.

Clusters were randomized to usual care or to the intervention including basic US at 16-22 and 32-36 wks with referrals for US-diagnosed conditions. Fetal, neonatal, maternal mortality and maternal near-miss, the primary composite outcome, were collected during ANC, at delivery and 42 days post-partum through an independent registry. US exam data were collected on women who had a study US.

**RESULTS:** Groups did not differ in use of ANC (RR 1.0 95% CI 1.00,1.01), the composite outcome (RR 1.09 95% CI 0.97,1.23), or the components (Table). After 2 wks of intensive training and a 3 mo pilot with all tests supervised, trainees performed quality basic exams. During the 18 mo trial, 78% of women delivering in the intervention clusters received at least 1 study US; 60% received 2. Conditions noted on US included twins, previa, oligo/polyhydramnios and abnormal lie. All were within expected ranges. 9% of women were referred for an US-diagnosed condition; 71% attended the referral.

**CONCLUSION:** US-naïve providers were successfully trained to conduct basic US exams. However, routine ANC US did not increase ANC use or hospital births nor did it improve the composite outcome or components. These LMIC results confirm Cochrane reviews of US in HIC. Introducing routine US in LMIC is unlikely to improve outcomes, would potentially pose a large burden on available resources, and detract from other more beneficial services.

First Look Trial Results in DRC, Kenya, Zambia, Guatemala and Pakistan, 2014-2016			
	Intervention	Control	RR (95% CI)
Study Clusters, N	29	29	
Women Enrolled, N	23,956	22,882	
Primary composite outcome, %	8.7	8.3	1.09 (0.97, 1.23)
Stillbirth, Rate/1000	27.8	27.0	1.08 (0.95, 1.24)
28-day NMR, Rate/1000	23.1	24.1	0.99 (0.86, 1.13)
Near miss, Rate/1000	48.3	44.9	1.11 (0.90, 1.37)
Maternal Death per 100,000	117	127	
Received at least one ANC visit, %	97.7	96.6	1.00 (1.00, 1.01)
ANC Visits ≥4, %	50.1	47.5	1.03 (0.90, 1.17)
Delivered at hospital with CS capacity, %	33.8	31.9	1.04 (0.86, 1.26)

### 4 Is magnesium sulfate use of benefit post partum? A randomized controlled trial



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**OBJECTIVE:** To determine if the use of Magnesium Sulfate (Mag) post delivery reduces the risk of eclampsia post partum in patients with severe preeclampsia that received at least 8 gm of Mag prior to delivery.

**STUDY DESIGN:** A randomized controlled trial was conducted in nine maternity hospitals in Latin America in patients with severe preeclampsia that had received at least 8gm of Mag prior to delivery. Sample size power calculation for non-inferiority required 1120 patients. 1113 patients were randomized. 555 patients to continue the infusion of IV Mag for 24 hours post partum and 558 were randomized to stopping the Mag infusion immediately post delivery. The primary outcome was the development of eclampsia in the first 24 hours post delivery. Secondary outcomes included maternal death

or complications, time to start ambulation and time to start lactation.

**RESULTS:** The maternal characteristics at randomization between the groups were no different including: gestational age, blood pressure, laboratory parameters, and the use of antihypertensives. No maternal deaths occurred in either group. There were no differences in the rate of eclampsia or maternal complications such as hemorrhage, respiratory depression and severe hypertension between the groups. Time to ambulation and time to lactation were significantly shorter in the no Mag group. (Table)

**CONCLUSION:** In this large randomized study the use of Mag for 24 hours post partum in patients with severe preeclampsia that had received at least 8 gm of Mag prior to delivery, was not associated with a reduction in eclampsia or other maternal complications post partum.

	Mag N=555	No Mag N=558	p value
Eclampsia N(%)	1(0.18)	2(0.35)	0.99
Hemorrhage N(%)	11(2.0)	13(2.3)	0.76
Resp. Depression N(%)	5(0.9)	4(0.7)	0.67
Severe HTN N(%)	53(9.5)	50(9.0)	0.60
Time to amb. (hours)	18.1 ± 10.6	11.8 ± 10.8	0.0001
Time to lact. (hours)	24.1 ± 17.1	17.1 ± 16.8	0.0001

**5 Enoxaparin for the prevention of preeclampsia and intrauterine growth restriction in women with a prior history (the eppi trial): an open-label international multicentre randomized controlled trial**

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**OBJECTIVE:** To determine whether daily enoxaparin commenced prior to 16+0 weeks' gestation, in addition to standard high risk care (SHRC), reduces the recurrence of pre-eclampsia and/or fetal growth restriction in women deemed to be at high risk of these conditions based on their past obstetric history.

**STUDY DESIGN:** An open-label randomised controlled trial in five obstetric units in New Zealand, Australia and the Netherlands. Inclusion criteria were:  $\geq 6^{+0}$  and  $\leq 15^{+6}$  weeks' gestation with fetal viability and singleton pregnancy confirmed, and most recent pregnancy complicated by (i) pre-eclampsia delivered  $\leq 35^{+6}$  weeks, (ii) small for gestational age (SGA)  $< 10^{th}$  customised birthweight centile (CBWC) delivered  $\leq 35^{+6}$  weeks, or (iii) SGA  $\leq 3^{rd}$  CBWC delivered at any gestation. Women were randomly assigned to SHRC plus enoxaparin 40mg subcutaneously daily or SHRC only. SHRC included prescription of daily low dose aspirin and calcium. Randomisation was stratified according to inherited thrombophilia status. Uterine and umbilical artery Doppler waveform studies were performed at 20 and 24 weeks' gestation and serum samples were taken for assessment of placental and angiogenic markers at recruitment, 20 and 30 weeks' gestation. The primary outcome was the incidence of pre-eclampsia and/or SGA  $< 5^{th}$  CBWC. Based on the available literature the sample

size was calculated to assess a reduction in the primary outcome from 25% to 7% (160 women required with 5% drop-out rate provides 80% power at a 2-sided significance level 0.05). This was an intention to treat analysis. ACTRN12609000699268.

**RESULTS:** Data were analysed for 156 women, 8 women delivered  $< 20$  weeks and were not included in further analysis. Preeclampsia and/or SGA  $< 5^{th}$  CBWC occurred in 35 women (23.5%). Enoxaparin in addition to SHRC did not reduce the rate of preeclampsia and/or SGA  $< 5^{th}$  CBWC (OR 1.17, 95%CI 0.5-2.6) or of any secondary outcomes (table).

**CONCLUSION:** In women with a prior pregnancy complicated by preeclampsia and/or fetal growth restriction, the addition of enoxaparin to high risk obstetric care did not reduce the risk of recurrence.

Outcome	SHRC plus enoxaparin (n=71)	SHRC (n=77)	Odds ratio (95%CI) or p value
Pre-eclampsia and/or SGA $< 5^{th}$ CBWC	18 (25%)	17 (22.1%)	1.17 (0.5-2.6)
Pre-eclampsia	6 (8.5%)	5 (6.5%)	1.28 (0.4-4.6)
SGA $< 5^{th}$ CBWC	15 (20.8%)	13 (16.9%)	1.35 (0.6-3.2)
SGA $< 10^{th}$ CBWC	23 (31.9%)	22 (28.6%)	1.16 (0.6-2.4)
Pre-eclampsia del $< 34+0$ weeks	2 (2.8%)	1 (1.3%)	2.02 (0.1-28.4)
Stillbirth/neonatal death	1 (1.4%)	3 (3.9%)	0.45 (0.04-5.7)
Mean gestational age at delivery (weeks + days)	37+5	37+1	p=0.45
Delivery $< 37$ weeks	15 (21.1%)	19 (25.0%)	p=0.70
Mean birthweight	2999g	2907g	p=0.50
Mean CBWC	32.0	31.3	p=0.87

**6 Prevention of preterm birth with pessary in singletons (PoPPS): a randomized controlled trial**

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**OBJECTIVE:** To determine if pessary use prevents preterm birth (PTB) in singleton gestations with a short transvaginal ultrasound (TVU) cervical length (CL) and without a prior spontaneous PTB.

**STUDY DESIGN:** Multicenter randomized controlled trial of asymptomatic women with singleton gestations with a TVU CL  $\leq 25$  mm at 18<sup>0</sup> - 23<sup>6</sup> weeks and no prior spontaneous PTB. Subjects were randomized to receive the Bioteque cup pessary or no pessary. Pessaries were inserted by MFM staff centrally trained in proper placement. Randomization was stratified by study site and CL ( $\leq 20$  mm or  $> 20$ -25mm). Treatment with vaginal progesterone was recommended to all women with a TVU CL  $\leq 20$  mm. Primary outcome was PTB  $< 37$  weeks. Composite adverse neonatal outcome included necrotizing enterocolitis, intraventricular hemorrhage (grade 3 or 4), respiratory distress syndrome, bronchopulmonary dysplasia, retinopathy, sepsis and neonatal death. Analysis was by intention-to-treat. Our required total sample size was 242. The trial was stopped prematurely by the DSMB due to the start of a competing NICHD MFMU pessary trial.

**RESULTS:** A total of 17,388 women were screened with TVU CL; 446 (2.6%) had a TVU CL  $\leq 25$  mm. Of the 394 (88.3%) who met eligibility criteria, 122 (31.0%) consented to randomization. As of the time of submission, 111 women have delivered, 56 (92%) in the pessary and 55 (90%) in the no pessary groups. Demographic characteristics, mean gestational age (21  $\pm$  1 week) and mean CL (16  $\pm$  7 mm) at enrollment were similar in both groups. There were no significant differences between the pessary and no pessary groups in rates of PTB  $< 37$  weeks, PTB  $< 34$  weeks, PTB  $< 28$  weeks, gestational