

Figure. Pregnancy outcomes of one-step vs two-step approach for GDM screening.

	One Step GDM screening (IADPSG) n= (%)	Two-Step GDM screening (ACOG) n= (%)	P-Value
Total	123	126	
GDM	10 (8.1)	7 (5.6)	0.42
GDM medically treated	5 (5.0)	4 (57.1)	0.77
LGA	3 (2.7)	5 (4.3)	0.51
IUGR	7 (6.3)	8 (6.9)	0.87
Polyhydramnios	6 (5.4)	4 (3.4)	0.46
PTB	12 (10.9)	10 (8.6)	0.56
Preeclampsia	10 (9.1)	9 (7.8)	0.78
CS rate	35 (31.8)	36 (31)	0.89
OVD	5 (4.5)	5 (4.3)	0.93
Shoulder dystocia	0 (0)	1 (0.9)	1.0
Macrosomia	9 (8.2)	7 (6.0)	0.53
Apgar 5<7	1/(0.9)	2 (1.7)	0.59
Neonatal Hypoglycemia	8 (7.3)	12 (10.3)	0.41
Hyperbilirubinemia	8 (7.3)	2 (1.7)	0.04
Fetal Demise >20 weeks	1 (0.9)	1 (0.8)	0.97

GDM-Gestational Diabetes Mellitus; LGA-Large for Gestational Age; IUGR: Intrauterine Growth Restriction; PTB- Preterm Birth; CS- Cesarean Section; OVD- Operative vaginal Delivery.

randomized to elective delivery at 34 weeks (ED) versus routine obstetric care (RC). The mode of delivery was not stipulated. The primary outcome measure was duration on total parenteral nutrition (TPN). Outcome variables were reported as mean (SD), median [range] or rate (%) and compared using appropriate statistical methods. The analysis was done according to intention to treat principle.

**RESULTS:** 21/25 (84%) eligible women were randomized; 10 to elective late preterm delivery and 11 to routine obstetric care (Fig). The trial was stopped at the first interim analysis after 21 of an expected 86 patients were enrolled (24%) for both patient safety concerns and for fertility. The median gestational age at delivery was 34.3 weeks [34, 36] in the ED group and 36.7 [27, 38] in the RC group. There was significantly more neonatal sepsis in the ED group than in the RC group (40% vs 0%, P=0.03). The number of days on TPN was non-significantly higher in the ED group [ED: 54 [17, 248] vs RC: 21 [9, 465] days, P= 0.08]. The time to closure of the gastroschisis was similar between the groups [ED: 7 [2, 21] vs RC: 5.5 [1, 8] days, P=0.18] (Table). The length of stay (LOS) was not statistically different [ED: 70.5 [22, 137] vs RC: 31 [19, 186], P= 0.15] (Table).

**CONCLUSION:** This study demonstrates no benefit of elective late preterm delivery of fetuses with gastroschisis when postnatal gastroschisis management is similar to that used in routine care. (ClinicalTrials.gov number, NCT01884324).

**40 Early delivery in fetal gastroschisis: a randomized controlled trial of elective 34 week delivery versus routine obstetrical care**

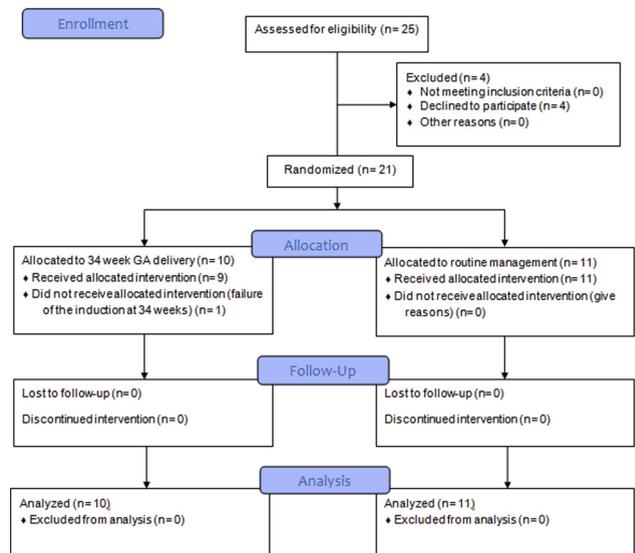


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**OBJECTIVE:** Hypothesis: Elective late preterm delivery of the fetus with gastroschisis may help limit injury to extruded fetal gut and thus promote faster recovery of neonatal gut function and earlier hospital discharge. We therefore compared outcomes of elective late preterm delivery (ED) with routine obstetric care (RC) in babies with gastroschisis.

**STUDY DESIGN:** Between May 2013 and September 2015, all women with a sonographically diagnosed gastroschisis referred to a single tertiary center before 34 weeks' gestation were invited to participate in this randomized controlled trial. Eligible patients were

CONSORT Flow Diagram for the Study



Baseline Characteristics of Recruited Cases			
	Early Delivery Group, N=10	Routine Care Group, N=11	
Maternal Age, mean(SD)	22.5 (7.1)	20.8 (3.2)	
Gravidity, median[range]	1.5 [1, 11]	1 [1, 3]	
Parity, median[range]	0.5 [0, 2]	0 [0, 1]	
GA at Diagnosis median[range]	19.5 [13, 28]	19.7 [12, 29]	
GA at Delivery median[range]	34.3 [34, 36]	36.7 [27, 38]	
BMI, mean(SD)	25.3 (5.1)	23.5 (1.7)	
Race, n (%)			
Caucasian	7	7	
African American	1	0	
Hispanic	2	4	
Asian	0	0	
Mode of Delivery, n (%)			
Vaginal	4 (induced:4)	7 (induced:5)	
CS	6 (induced:2)	4 (induced:2)	
Male Fetus, n (%)	4	5	
Tobacco Use, n (%)	3	4	
Primary and Secondary Outcomes			
			P-Value
Primary Outcome			
Duration of TPN(day), median[range]	54 [17, 248]	21 [9, 465]	0.08
Secondary Outcomes			
Time to Closure(day), median[range]	7 [2, 21]	5.5 [1, 8]	0.18
Hospital Stay(day), median[range]	70.5 [22, 137]	31 [19, 186]	0.15
Early Neonatal Outcomes			
Birth Weight(g), mean(SD)	2110 (296)	2615 (469)	0.01
Primary Closure, n (%)	1 (10%)	1 (9.1%)	1.00
Total Intubation Time(day), median[range]	4 [1, 14]	3 [1, 13]	0.44
Nasal O2 Time(day), median[range]	6 [2, 10]	1.2 [1, 7]	0.07
Surfactant, n (%)	1 (10%)	0	0.5
NEC, n (%)	0	0	-
BPD, n (%)	0	0	-
RDS, n (%)	0	0	-
Sepsis, n (%)	4 (40%)	0	0.03
Apgar 5 < 7, n (%)	0	0	-

GA = gestational age; BMI = body mass index; NEC= necrotizing enterocolitis; BPD = bronchopulmonary dysplasia; RDS = respiratory distress syndrome  
Values are presented as mean (SD) (independent t-test), median (range) (Mann-Whitney U test) and n (%) (Chi square test).

## 41 A randomized control trial on the effect of introducing a daily smartphone based feedback system between GDM patients and physicians- on patient compliance, glycemic control, satisfaction, and pregnancy outcome



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**OBJECTIVE:** To study the impact of introducing a smartphone-based daily communication platform between gestational diabetes mellitus (GDM) patients and their physicians, on patients compliance, glycemic control, satisfaction, and pregnancy outcome.

**STUDY DESIGN:** This is a prospective, single-center, randomized controlled trial. Newly diagnosed GDM patients presenting to our multidisciplinary diabetes-in-pregnancy clinic were randomized to: (1) routine bi-weekly prenatal clinic care (control group) or (2) an additional daily detailed feedback on their compliance and glycemic control from the clinic team via an application installed on their smartphone (smartphone group). The primary outcome was patient compliance defined as the actual blood glucose measurements/instructed measurements X100. The secondary outcomes included diabetes-control parameters, pregnancy, and neonatal outcomes. The

study was adequately powered to detect a 20% difference in patient compliance, based on a preliminary phase that demonstrated 70% baseline compliance to glucose measurements.

**RESULTS:** A total of 120 newly diagnosed GDM patients were randomized. The two groups did not differ in terms of age, parity, education, BMI, family history, maternal diseases, OGTT values, and HbA1C at randomization. The smartphone group demonstrated higher level of compliance (82% vs. 67%,  $p<0.001$ ), lower mean blood glucose ( $104.7 \pm 9.1$  mg/dl vs.  $112.6 \pm 8.6$  mg/dl,  $p<0.001$ ), lower rates of off-target measurements both fasting (7.6% vs. 14.3%,  $p<0.001$ ) and post-prandial (4.7% vs. 8.3%,  $p<0.001$ ), and a lower rate of pregnancies requiring insulin treatment (11.6% vs. 28.3%,  $p=0.038$ ). The rates of macrosomia, neonatal hypoglycemia, shoulder dystocia and other delivery and neonatal complications did not differ between the groups. Patients in the smartphone group reported excellent satisfaction from the use of the application and from their overall prenatal care.

**CONCLUSION:** Introduction of a smartphone-based daily feedback and communication platform between GDM patients and the multidisciplinary diabetes-in-pregnancy clinic team, improved patient compliance, glycemic control, and the rate of insulin treatment.

	Smart-phone group n=60	Control group n=60	p-value
<b>Glycemic control</b>			
Compliance	82 ± 0.16	67 ± 0.27	<0.001
Mean blood glucose (mg/dl)	104.7±9.1	112.6 ± 8.6	<0.001
Off-target (>120 mg/dl) post prandial glucose measurements (%)	7.6 ± 0.8	14.3 ± 0.9	<0.001
Off-target (>90 mg/dl) fasting glucose measurements (%)	4.7 ± 0.4	8.3 ± 0.5	<0.001
Patients requiring insulin treatment (%)	7 (11.6%)	17 (28.3%)	0.038
<b>Pregnancy and delivery outcomes</b>			
Gestational age at delivery (weeks)	38.11±1.76	38.45±1.45	0.250
Cesarean delivery (%)	10 (16.6%)	17 (28.3%)	0.190
Polyhydramnios (%)	0	4 (6.6%)	0.120
<b>Neonatal outcome</b>			
Birth weight (grams)	3074±550	3188±420	0.204
LGA (%)	6 (10%)	6 (10%)	1.000
NICU admission (%)	4 (6.6%)	7 (11.6%)	0.528
Composite adverse neonatal outcome (%)	7 (11.6%)	11 (18.3%)	0.443

LGA = large for gestational age (birthweight > 90<sup>th</sup> percentile), NICU = neonatal intensive care unit. Values in bold are statistically significant  
Compliance=actual blood glucose measurements/instructed measurements X100

