

SUGAR-DIP trial

Oral medication strategy versus insulin for diabetes in pregnancy

Electronic case report form

CRF data entry and randomization:

www.castoredc.com

- o Single possible answer
- ☐ Multiple answers possible

General information	
Maternal age at time of randomization	(years)
Estimated date of delivery	(dd-mm-yyyy)
In-exclusion	
Age 18 years or older	o Yes
	o No
Singleton pregnancy	o Yes
	o No
Diagnosis if gestational diabetes mellitus as per	o Yes
national guidelines	o No
Indication for pharmacological treatment of GDM	o Yes
	o No
Gestational age between 16 and 34 weeks	o Yes
	o No
Ability to understand Dutch or English	o Yes
	o No
Known pre-existent type I or II diabetes mellitus	o Yes
	o No
Severe medical or psychological comorbidity	o Yes
	o No
Liver disease or kidney failure, or any other	o Yes
condition with contraindications for the use of	o No
either metformin or glibenclamide	
Fetus with major congenital birth defect and/or	o Yes
chromosomal abnormality	o No
Informed consent & Randomization	
Patient has provided written informed consent	o Yes
	o No
Date of informed consent	(dd-mm-yyyy)
Date of randomization	(dd-mm-yyyy)
Gestational age at time of randomization	weeks + days
Medical history	
Ethnicity	Caucasian/white
	o Indian/Pakistani/Bangladesi/Hindu
	Black/African (Sub-Sahara)
	Middle Eastern + North African Trades Manager Francisco
	(Turkey, Morocco, Egypt)
	o Asian
	o Other
Diagnosis of Dolysystis Overs Overstones	o Unknown
Diagnosis of Polycystic Ovary Syndrome	o Yes
(PCOS)	o No
Thyroid problems: hypo- or hyperthyroidism	Hypothyroidism Hyporthyroidism
	 Hyperthyroidism

History of psychological problems History of psychological problems Depression Anxiety disorder Burn-out Other None Unknown Maternal chronic or pre-existent hypertension Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during pregnancy Maternal medication use (other than folic acid and vitamins) during medication) No Unknown SRI (including sertraline, (es)citalopram, paroxetine, fluoxetine) Tricyclic antidepressant (including amitryptilline, nortryptilline) Other Unknown Family history of gestational diabetes mellitus (1st or 2st degree) No Unknown Family history if hypertension (1st or 2st degree) No Unknown Family history of preeclampsia (1st or 2st degree) No Unknown Family history of congenital defects (1st or 2st degree) No Unknown Family history of congenital defects (1st or 2st degree) No Unknown Family history of congenital defects (1st or 2st degree) No Unknown Family history of congenital defects (1st or 2st degree) No Unknown Family history of congenital defects (1st or 2st degree) No Unknown Family history of preeclampsia (1st or 2st degree) No Unknown Family history of preeclampsia (1st or 2st degree) No Unknown Family history of preeclampsia (1st or 2st degree) No Unknown Family history of preeclampsia (1st or 2st degree) No Unknown Family history of pree		
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diabetes mellitus? o Yes	Intra-uterine death > 16 weeks	(n)
	Any previous pregnancy with gestational	 No (no GDM in previous pregnancies)
o Unknown	diabetes mellitus?	o Yes
		o Unknown

How many pregnancies with gestational diabetes	(n)
mellitus?	
Any pregnancy with GDM treated with insulin?	o No
	o Yes
	o Unknown
Any previous pregnancy with pregnancy induced	 No (no PIH in previous pregnancies)
hypertension (PIH)?	o Yes
	o Unknown
Any previous pregnancy with preeclampsia	 No (no PE in previous pregnancies)
(PE)?	o Yes
	o Unknown
Any previous pregnancy with Hemolysis	 No (no HELLP in previous
Elevated Liver enzymes and Low Platelets	pregnancies)
syndrome (HELLP)?	o Yes
	o Unknown
Any previous pregnancy with a preterm delivery	 No (no preterm delivery in previous
(< 37 weeks of gestation)	pregnancies)
	o Yes
	o Unknown
A caesarean section (primary or secondary) in	 No (no caesarean section in the past)
the past?	o Yes
	o Unknown
Any hemorrhagia postpartum (HPP, blood loss ≥	 No (no HPP in the past)
1000ml) in the past?	o Yes
	o Unknown
Please complete the following questions for all	Parity number:
previous pregnancies > 16 weeks	Gestational age: weeks + days
	Gender: male, female, unknown
C	Birth weight (grams):
Current pregnancy	0
Mode of conception	o Spontaneous
	Clomifene ovulation induction
	Intra-uterine insemination (IUI)IVF / ICSI
	Egg cell donation Unknown
Maternal height	o Unknown
Maternal height at start of pregnancy	(cm) (kg)
Maternal weight at time of study inclusion	
Maternal weight at time of study inclusion Maternal weight at time of delivery / last pre-	(kg)
delivery visit	(kg)
Maternal weight gain (total) >12kg	o Yes
waternar weight gain (total) > 12kg	
Maternal blood pressure systolic at first	O Unknown (mmHg)
antenatal visit	(IIIIIII)
Maternal blood pressure diastolic at first	(mmHg)
antenatal visit	(IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII
Smoking during pregnancy	o No
omoking during pregnancy	o N0

o Quit in first trimester Quit later in pregnancy Yes (still smoking) Unknown Alcohol use during pregnancy Alcohol use during pregnancy O Yes No Unknown Glucose value (random) in first trimester Diagnostic test used to determine gestational diabetes O Cral glucose tolerance test (75 gram) Oral glucose tolerance test (100 gram) Fasting glucose level Glucose value of 75 gram OGTT fasting (laboratory) Glucose value of 75 gram OGTT phours (laboratory) Glucose value of 75 gram OGTT 2 hours (laboratory) Glucose value of 100 gram OGTT 2 hours (laboratory) Glucose value of 100 gram OGTT 2 hours (laboratory) Glucose value of 100 gram OGTT 3 hours (laboratory) Glucose value of 100 gram OGTT 3 hours (laboratory) Glucose value fasting (laboratory) Glucose value fasting (laboratory) Glucose value of 100 gram OGTT 3 hours (laboratory) Glucose value of 100 gram OGTT 3 hours (laboratory) Glucose value fasting (laboratory) Family history with diabetes Obesity Prior pregnancy with GDM Ethnicity Other Unknown Pregnancy complications Pregnancy induced hypertension (systolic BP > 140mmHg or diastolic BP > 90mmHg) O With undication (for instance labetolol or methyldopa) Unknown whether medication was used Other Preeclampsia (hypertension with albuminuria) Preeclampsia (hypertension with albuminuria) O Quit in first timester O Pres O Ves O Cher	Alcohol use during pregnancy Alcoho	
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o Other Preeclampsia (hypertension with albuminuria) o Yes	o Other	
Preeclampsia (hypertension with albuminuria) o Yes		
, , , , ,	TOTOGRAPHORIA CHANGE CONTROLL WILLIAM CHANGE CONTROLL CONTROL	
I O INU	, , , , ,	
o Unknown		
HELLP o Yes		
	o No	

	o Unknown
Trombo embolio complications (does vesque	
Trombo-embolic complications (deep venous	
thrombosis or lung-embolus)	
	o Unknown
Hospital admission because of severe glycemic	o Yes
dysregulation	o No
	o Unknown
Fetal structural defects (ultrasound)	o Yes
	o No
	o Unknown
Fetal structural defects (ultrasound)	 □ Central nervous system, including spina bifida and anencephaly □ Skeletal system, including caudal
	regression syndrome, limb defects and sacral agenesis
	 Cardiovascular, including transposition of the great vessels, septal defects, single umbilical artery (SUA),
	coarctation of the aorta Gastrointestinal, including duodenal atresia
	☐ Unknown which system☐ Other
Magrapagia (FF)M, 200 at FAC, 200 at	
Macrosomia (EFW >p90 or FAC >p90 or	o Yes
mentioned in conclusion)	o No
	o Unknown
Intra-uterine growth restriction (IUGR) (EFW	o Yes
<p10 <p10="" conclusion)<="" fac="" in="" mentioned="" or="" td=""><td>o No</td></p10>	o No
	o Unknown
Polyhydramnios (ultrasound)	o Yes
	o No
	o Unknown
Oligohydramnios (ultrasound)	o Yes
	o No
	o Unknown
Corticosteroid used? (for instance because of	o Yes
imminent premature birth)	o No
·	o Unknown
Intra-uterine death	o Yes
	o No
Date of intra-uterine death	(dd-mm-yyyy)
Delivery	(),,,,,
Date of last dose of antidiabetic medication	(dd-mm-yyyy)
Time of last dose of antidiabetic medication	(hh-mm)
Onset of labour	
	l 5.
Was industion planned for a different reason	
Was induction planned for a different reason	
than gestational diabetes mellitus?	o No

	o Unknown
Reason for induction	□ Elective
	□ Ruptured membranes
	□ Hypertension
	□ Preeclampsia
	☐ HELLP syndrome
	☐ Maternal: blood glucose dysregulation
	☐ Maternal: other → specify
	□ Fetal: suspected macrosomia
	☐ Fetal: suspected intra-uterine growth
	restriction
	□ Fetal: no movements
	☐ Fetal: heart rate anomaly
	☐ Fetal: near rate anomaly ☐ Fetal: oligohydramnios
	□ Fetal: meconium
	☐ Fetal: meconium ☐ Fetal: other → specify
Method of induction	 □ Other → specify □ Foley catheter / mechanical
Method of induction	
	1
	☐ Amniotomy
	□ Oxytocin
	☐ Other
Ladia Can fan minama a a a a can a a a Can	□ Unknown
Indication for primary caesarean section	☐ Elective: breech
	☐ Elective: obstetric history (previous
	caesarean section)
	☐ Elective: obstetric history (total
	sphincter rupture)
	☐ Elective: obstetric history (other)
	☐ Fetal distress
	☐ Fetal: intra-uterine growth restriction
	□ Fetal: other
	☐ Maternal: hypertension
	☐ Maternal: preeclampsia
	☐ Maternal: HELLP syndrome
	☐ Maternal: other
B : " () : 1 !!	☐ Unknown
Pain relief during delivery	□ None
	☐ Opioid subcutaneous (pethidine)
	Opioid intravenous (remifentanil)
	□ Nitrous oxide
	□ Epidural
	☐ Other
Madia Canadania a L.	□ Unknown
Medication during labour	□ Oxytocin
	☐ Antibiotics
	☐ Tocolytics
	☐ Glucose/insulin intravenous
	☐ Antihypertensive agents intravenous
	□ Other → specify

	□ None
	□ Unknown
Fever during delivery	M
Fever during delivery	
	o Yes (>38°C <38.5°C)
	o Yes (≥38.5°C)
	o Unknown
Fetal presentation	o Cephalic
	o Breech
	o Other
Route of delivery	o Vaginal, spontaneously
	Instrumental (vacuum extraction)
	 Instrumental (forcipal extraction)
	Secondary caesarean section
Indication for vacuum / forcipal extraction	o Fetal distress
	 Failure to progress
	 Maternal indication
	 Other fetal indication
	o Unknown
Indication for secondary caesarean section	 Fetal distress
	 Failure to progress
	 Failed induction
	 Maternal indication
	 Failed vacuum / forcipal extraction
	 Other fetal indication
	o Unknown
Were maneuvers used because of shoulder	□ No (no shoulder dystocia)
dystocia?	 Traction to the fetal head
	□ McRoberts
	□ Rubin
	□ All-fours
	 Manual delivery of posterior arm
	 Intentional breaking of clavicle
	☐ Shoulder dystocia but unknown which
	maneuvers were used
	☐ Other
Amniotic fluid	o Clear
	 Meconium stained
	o Unknown
Delivery of the placenta	 Spontaneously / controlled cord
	traction
	 Manual removal in operating room
	 Removed during caesarean section
	o Unknown
Total blood loss	(ml)
Blood transfusion	o Yes
	o No
	o Unknown
Perineum	□ No laceration(s)
	☐ First / second degree laceration(s)

Episiotomy Unknown		☐ Third degree laceration(s)
Neonatal data Date of birth Date of birthh		
Date of birth		□ Unknown
Cestational age at birth		
Live birth Neonatal death Neonatal congenital malformation: neural tube Neonatal congenital malformation: other Neonatal glucose postpartum Neonatal glucose postpartum Neonatal glucose postpartum Neonatal congenital malformation: other Neonatal congenital malformation: other Neonatal congenital malformation: other Neonatal glucose postpartum Neonatal glucose testing postpartum Neonatal congenital malformation: other		
Neonatal death		•
Neonatal death O No Yes (intra-uterine death) O Yes, <24 hours postpartum O Yes, >24 hours postpartum O Yes, >24 hours postpartum O Male O Unknown Apgar score 1 minute postpartum Apgar score 5 minutes postpartum Apgar score 10 minutes postpartum Umbilical cord blood pH (arterial) Umbilical cord blood base excess (arterial) Umbilical cord blood base excess (arterial) Umbilical cord blood base excess (venous) Birth weight Fracture O None Humerus Clavicle Other Unknown Erbs palsy No Yes Unknown Preterm birth (<37 weeks of gestation) No Yes (iatrogenic) Yes (spontaneous) No Yes Unknown No No No Yes Unknown No	Live birth	
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O Unknown First neonatal glucose postpartum Date of first neonatal glucose testing postpartum (dd-mm-yyyy)	Neonatal congenital mailornation. other	
First neonatal glucose postpartum (mmol/L) Date of first neonatal glucose testing postpartum (dd-mm-yyyy)		
Date of first neonatal glucose testing postpartum (dd-mm-yyyy)	First neonatal dlucose postnartum	†
		1

Second neonatal glucose value postpartum	(mmol/L)
Date of second neonatal glucose testing	(dd-mm-yyyy)
postpartum	(da-min-yyyy)
Time of second neonatal glucose testing	(hh:mm)
1	(1111.11111)
postpartum Third page to a supply a page to artism.	//no.mo.o.l/L \
Third neonatal glucose value postpartum	(mmol/L)
Date of third neonatal glucose testing	(dd-mm-yyyy)
postpartum	/11
Time of third neonatal glucose testing	(hh:mm)
postpartum	
Fourth neonatal glucose value postpartum	(mmol/L)
Date of fourth neonatal glucose testing	(dd-mm-yyyy)
postpartum	
Time of fourth neonatal glucose testing	(hh:mm)
postpartum	
Fifth neonatal glucose value postpartum	(mmol/L)
Date of fifth neonatal glucose testing postpartum	(dd-mm-yyyy)
Time of fifth neonatal glucose testing postpartum	(hh:mm)
Sixth neonatal glucose value postpartum	(mmol/L)
Date of sixth neonatal glucose testing	(dd-mm-yyyy)
postpartum	, , , , , , , , , , , , , , , , , , , ,
Time of sixth neonatal glucose testing	(hh:mm)
postpartum	,
Any neonatal glucose value between 2.0-	o No
2.6mmol/L (>2.0 <2.7) during in hospital	 Yes, one value between 2.0 and 2.6
admission?	 Yes, more than one value between 2.0
	and 2.6
	o Unknown
Any neonatal glucose value <2.0mmol/L during	o No
hospital admission?	Yes, one value <2.0
Troophal admission.	Yes, more than one value <2.0
	o Unknown
Postpartum	O CHILIOWII
Were mother or child admitted directly	 No (mother and child went home
postpartum? (including postpartum observation	directly after delivery
of mother/child)	Van van (amar) a dania dan andre
or mother/critica)	
	· · · · · · · · · · · · · · · · · · ·
Matawall what was the vesser for admission?	o Yes, neonatal admission only
Maternal: what was the reason for admission?	☐ Maternal observation/routine stay (for
	instance because of more blood loss
	than usual or post-caesarean)
	□ Neonatal observation (for instance
	because of blood glucose evaluation)
	☐ Fluxus (HPP)
	☐ Pregnancy induced hypertension
	□ Preeclampsia
	☐ HELLP syndrome
	☐ Glycemic dysregulation
	☐ Thrombo-embolic event

	☐ Hemodynamically unstable (Intensive)
	Care)
	□ Infection
	☐ Other
Maternal: type of admission	o Ward
	o Medium Care
	 Intensive Care
Maternal: discharge to	o Home
	 Other ward
	o Medium Care
	o Intensive Care
	Other hospital
Maternal: date of transfer	(dd-mm-yyyy)
Maternal: type of admission after transfer	o Ward
	o Medium Care
	o Intensive Care
Maternal: date of final discharge to home	(dd-mm-yyyy)
Neonatal: what was the reason for admission?	☐ Routine observation for blood glucoses
	□ Routine observation for meconium
	□ Routine observation for suspected
	infection
	☐ Hypoglycemia without i.v. glucose
	☐ Hypoglycemia with iv glucose
	☐ Hyperbilirubinemia with phototherapy
	☐ Hyperbilirubinemia without
	phototherapy
	□ Respiratory distress syndrome (RDS) /
	respiratory support or oxygen >24
	hours
	☐ Broncho pulmonal dysplasia (BPD)
	☐ Intraventricular haemorrhage
	☐ Sepsis
	□ Necrotizing enterocolitis□ Convulsions
	□ Trombocyte transfusion□ Prematurity
	□ Asphyxia
	□ Other
Neonatal: type of admission	o Ward
1 Neonatal: type of admission	Medium Care
	Intensive Care
Neonatal: discharge to	o Home
1400 natal. disonarge to	o Ward
	Medium Care
	o Intensive Care
Neonatal: date of transfer	(dd-mm-yyyy)
Neonatal: type of admission after transfer	o Ward
Trochatal type of daminosion after transfer	Medium Care

	 Intensive Care
Neonatal: date of final discharge to home	(dd-mm-yyyy)
Neonatal weight at time of discharge	(grams)
Did the neonate receive iv glucose infusion	o Yes
postpartum?	o No
postpartum:	o Unknown
How many days of iv glucose infusion?	(days)
Diabetes treatment	(44)0)
What treatment was the participant randomized	o Insulin
to?	 Oral hypoglycemic agents
Did the participant ever use: metformin	o Yes
	o No
	 Unknown
On which date did the participant start with metformin?	(dd-mm-yyyy)
	(dd mm yaaa)
On which date did the participant stop with metformin?	(dd-mm-yyyy)
Did the participant ever use: glibenclamide	o Yes
Did the participant ever use, glibericiamide	o No
	o Unknown
On which date did the participant start with	(dd-mm-yyyy)
glibenclamide?	, , , , , , , , , , , , , , , , , , , ,
On which date did the participant stop with	(dd-mm-yyyy)
glibenclamide?	
Did the participant ever use: insulin?	o Yes
	o No
	o Unknown
On which date did the participant start with insulin?	(dd-mm-yyyy)
(If multiple types of insulin were used, use the	
start date of the first type of insulin)	(dd mm yaaa)
On which date did the participant stop with insulin?	(dd-mm-yyyy)
(If multiple types of insulin were used, use the	
start date of the first type of insulin)	
Glucose profile most recent before or at	(mmol/L)
randomization: fasting value	(IIIIIIO)/L)
Glucose profile most recent before or at	(mmol/L)
randomization: after breakfast value	(1111101/2)
Glucose profile most recent before or at	(mmol/L)
randomization: after lunch value	(
Glucose profile most recent before or at	(mmol/L)
randomization: after dinner value	(············
Most recent HbA1c value before or at	(mmol/mol)
randomization	('33.1.5)
Date of most recent HbA1c value before or at	(dd-mm-yyyy)
randomization	, , , , , , , , , , , , , , , , , , , ,
HbA1c value at 30-31 weeks of gestation	(mmol/mol)
Date of HbA1c value at 30-31 weeks of gestation	(dd-mm-yyyy)

HbA1c value at 35-36 weeks of gestation	(mmol/mol)
Date of HbA1c value at 35-36 weeks of gestation	(dd-mm-yyyy)
Additional tests	(0.0.1
Umbilical cord blood C-peptide value	(pmol/L)
Umbilical cord blood glucose value	(mmol/L)
Umbilical cord blood insulin value	(mIU/L)
Umbilical cord blood fructosamine value	(µmol/L)
Umbilical cord blood triglycerides	(mmol/L)
End of study	
Was there a protocol violation?	o No
·	o Yes
	 Unknown
Did a Serious Adverse Event (SAE) occur during	o No
the study until 6 weeks postpartum?	o Yes
(If yes, please report the SAE to the sponsor)	o Unknown
Did a Suspected Unexpected Serious Adverse	o No
Reaction (SUSAR) occur during the study until 6	o Yes
weeks postpartum?	o Unknown
(If yes, please report the SUSAR to the sponsor)	
Please specify if the subject completed the entire	o Completed
course of the study as specified in the study	o Discontinued
protocol or discontinued the study:	Cubicat violetes and an manual of the
If discontinued, please specify the most	 Subject violates one or more of the inclusion/exclusion criteria
appropriate reason for early termination	A 1
	Deutlebeert deserved
	Participant deceased Participant lost to follow up
	 Participant lost to follow up Participant withdrew consent to use
	personal data
	 Investigator's and/or physician's
	decision
	 Total study is early terminated
	 Other reason
Has the participant signed informed consent for	o Yes
follow-up?	o No
Has the participant provided contact information	o Yes
to allow follow-up?	o No