



# SUGAR-DIP trial

Oral medication strategy versus insulin for diabetes in pregnancy

Electronic case report form

CRF data entry and randomization:

[www.castoredc.com](http://www.castoredc.com)

- Single possible answer
- Multiple answers possible

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

	<ul style="list-style-type: none"> <li>○ Thyroid problem, but type is unknown</li> <li>○ No</li> <li>○ Unknown</li> </ul>
History of psychological problems	<ul style="list-style-type: none"> <li><input type="checkbox"/> Depression</li> <li><input type="checkbox"/> Anxiety disorder</li> <li><input type="checkbox"/> Burn-out</li> <li><input type="checkbox"/> Other</li> <li><input type="checkbox"/> None</li> <li><input type="checkbox"/> Unknown</li> </ul>
Maternal chronic or pre-existent hypertension	<ul style="list-style-type: none"> <li>○ Yes (requiring medication)</li> <li>○ Yes (not requiring medication)</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Maternal medication use (other than folic acid and vitamins) during pregnancy	<ul style="list-style-type: none"> <li><input type="checkbox"/> No</li> <li><input type="checkbox"/> Aspirin (Acetylsalicylic acid)</li> <li><input type="checkbox"/> Levothyroxine / Thyrox</li> <li><input type="checkbox"/> SSRI (including sertraline, (es)citalopram, paroxetine, fluoxetine)</li> <li><input type="checkbox"/> Tricyclic antidepressant (including amitriptyline, nortriptyline)</li> <li><input type="checkbox"/> Other</li> <li><input type="checkbox"/> Unknown</li> </ul>
<b>Family history</b>	
Family history of type I / type II diabetes mellitus (1 <sup>st</sup> or 2 <sup>nd</sup> degree)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Family history of gestational diabetes mellitus (1 <sup>st</sup> or 2 <sup>nd</sup> degree)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Family history of hypertension (1 <sup>st</sup> or 2 <sup>nd</sup> degree)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Family history of preeclampsia (1 <sup>st</sup> or 2 <sup>nd</sup> degree)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Family history of congenital defects (1 <sup>st</sup> or 2 <sup>nd</sup> degree)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
<b>Obstetric history</b>	
Gravidity	(n)
Parity	(n)
Living children	(n)
Miscarriage – spontaneous abortion	(n)
Abortus provocatus – induced abortion	(n)
Extra-uterine gravidity	(n)
Intra-uterine death > 16 weeks	(n)
Any previous pregnancy with gestational diabetes mellitus?	<ul style="list-style-type: none"> <li>○ No (no GDM in previous pregnancies)</li> <li>○ Yes</li> <li>○ Unknown</li> </ul>

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

	<ul style="list-style-type: none"> <li><input type="radio"/> Quit in first trimester</li> <li><input type="radio"/> Quit later in pregnancy</li> <li><input type="radio"/> Yes (still smoking)</li> <li><input type="radio"/> Unknown</li> </ul>
Alcohol use during pregnancy	<ul style="list-style-type: none"> <li><input type="radio"/> Yes</li> <li><input type="radio"/> No</li> <li><input type="radio"/> Unknown</li> </ul>
Glucose value (random) in first trimester	(mmol/L)
Diagnostic test used to determine gestational diabetes	<ul style="list-style-type: none"> <li><input type="radio"/> Oral glucose tolerance test (75 gram)</li> <li><input type="radio"/> Oral glucose tolerance test (100 gram)</li> <li><input type="radio"/> Fasting glucose level</li> <li><input type="radio"/> Glucose day curve</li> <li><input type="radio"/> Other</li> </ul>
Date of GDM diagnosis	(dd-mm-yyyy)
Glucose value of 75 gram OGTT fasting (laboratory)	(mmol/L)
Glucose value of 75 gram OGTT 2 hours (laboratory)	(mmol/L)
Glucose value of 100 gram OGTT fasting (laboratory)	(mmol/L)
Glucose value of 100 gram OGTT 2 hours (laboratory)	(mmol/L)
Glucose value of 100 gram OGTT 3 hours (laboratory)	(mmol/L)
Glucose value fasting (laboratory)	(mmol/L)
Highest glucose value of glucose day curve	(mmol/L)
Main reason to perform OGTT	<ul style="list-style-type: none"> <li><input type="radio"/> Suspected macrosomia/estimated fetal weight &gt;p90 (current pregnancy)</li> <li><input type="radio"/> Family history with diabetes</li> <li><input type="radio"/> Obesity</li> <li><input type="radio"/> Prior pregnancy with GDM</li> <li><input type="radio"/> Ethnicity</li> <li><input type="radio"/> Other</li> <li><input type="radio"/> Unknown</li> </ul>
<b>Pregnancy complications</b>	
Pregnancy induced hypertension (systolic BP > 140mmHg or diastolic BP > 90mmHg)	<ul style="list-style-type: none"> <li><input type="radio"/> Yes</li> <li><input type="radio"/> No</li> <li><input type="radio"/> Unknown</li> </ul>
Pregnancy induced hypertension	<ul style="list-style-type: none"> <li><input type="radio"/> Without medication</li> <li><input type="radio"/> With medication (for instance labetalol or methyldopa)</li> <li><input type="radio"/> Unknown whether medication was used</li> <li><input type="radio"/> Other</li> </ul>
Preeclampsia (hypertension with albuminuria)	<ul style="list-style-type: none"> <li><input type="radio"/> Yes</li> <li><input type="radio"/> No</li> <li><input type="radio"/> Unknown</li> </ul>
HELLP	<ul style="list-style-type: none"> <li><input type="radio"/> Yes</li> <li><input type="radio"/> No</li> </ul>

	<ul style="list-style-type: none"> <li>○ Unknown</li> </ul>
Trombo-embolic complications (deep venous thrombosis or lung-embolus)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Hospital admission because of severe glycaemic dysregulation	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Fetal structural defects (ultrasound)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Fetal structural defects (ultrasound)	<ul style="list-style-type: none"> <li><input type="checkbox"/> Central nervous system, including spina bifida and anencephaly</li> <li><input type="checkbox"/> Skeletal system, including caudal regression syndrome, limb defects and sacral agenesis</li> <li><input type="checkbox"/> Cardiovascular, including transposition of the great vessels, septal defects, single umbilical artery (SUA), coarctation of the aorta</li> <li><input type="checkbox"/> Gastrointestinal, including duodenal atresia</li> <li><input type="checkbox"/> Unknown which system</li> <li><input type="checkbox"/> Other</li> </ul>
Macrosomia (EFW >p90 or FAC >p90 or mentioned in conclusion)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Intra-uterine growth restriction (IUGR) (EFW <p10 or FAC <p10 or mentioned in conclusion)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Polyhydramnios (ultrasound)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Oligohydramnios (ultrasound)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Corticosteroid used? (for instance because of imminent premature birth)	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> <li>○ Unknown</li> </ul>
Intra-uterine death	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>
Date of intra-uterine death	(dd-mm-yyyy)
<b>Delivery</b>	
Date of last dose of antidiabetic medication	(dd-mm-yyyy)
Time of last dose of antidiabetic medication	(hh-mm)
Onset of labour	<ul style="list-style-type: none"> <li>○ Spontaneously</li> <li>○ Primary caesarean section</li> <li>○ Induction</li> </ul>
Was induction planned for a different reason than gestational diabetes mellitus?	<ul style="list-style-type: none"> <li>○ Yes</li> <li>○ No</li> </ul>

	<input type="radio"/> Unknown
Reason for induction	<input type="checkbox"/> Elective <input type="checkbox"/> Ruptured membranes <input type="checkbox"/> Hypertension <input type="checkbox"/> Preeclampsia <input type="checkbox"/> HELLP syndrome <input type="checkbox"/> Maternal: blood glucose dysregulation <input type="checkbox"/> Maternal: other → specify <input type="checkbox"/> Fetal: suspected macrosomia <input type="checkbox"/> Fetal: suspected intra-uterine growth restriction <input type="checkbox"/> Fetal: no movements <input type="checkbox"/> Fetal: heart rate anomaly <input type="checkbox"/> Fetal: oligohydramnios <input type="checkbox"/> Fetal: meconium <input type="checkbox"/> Fetal: other → specify <input type="checkbox"/> Other → specify
Method of induction	<input type="checkbox"/> Foley catheter / mechanical <input type="checkbox"/> Prostaglandins <input type="checkbox"/> Amniotomy <input type="checkbox"/> Oxytocin <input type="checkbox"/> Other <input type="checkbox"/> Unknown
Indication for primary caesarean section	<input type="checkbox"/> Elective: breech <input type="checkbox"/> Elective: obstetric history (previous caesarean section) <input type="checkbox"/> Elective: obstetric history (total sphincter rupture) <input type="checkbox"/> Elective: obstetric history (other) <input type="checkbox"/> Fetal distress <input type="checkbox"/> Fetal: intra-uterine growth restriction <input type="checkbox"/> Fetal: other <input type="checkbox"/> Maternal: hypertension <input type="checkbox"/> Maternal: preeclampsia <input type="checkbox"/> Maternal: HELLP syndrome <input type="checkbox"/> Maternal: other <input type="checkbox"/> Unknown
Pain relief during delivery	<input type="checkbox"/> None <input type="checkbox"/> Opioid subcutaneous (pethidine) <input type="checkbox"/> Opioid intravenous (remifentanyl) <input type="checkbox"/> Nitrous oxide <input type="checkbox"/> Epidural <input type="checkbox"/> Other <input type="checkbox"/> Unknown
Medication during labour	<input type="checkbox"/> Oxytocin <input type="checkbox"/> Antibiotics <input type="checkbox"/> Tocolytics <input type="checkbox"/> Glucose/insulin intravenous <input type="checkbox"/> Antihypertensive agents intravenous <input type="checkbox"/> Other → specify

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



	<input type="checkbox"/> Third degree laceration(s) <input type="checkbox"/> Episiotomy <input type="checkbox"/> Unknown
<b>Neonatal data</b>	
Date of birth	(dd-mm-yyyy)
Gestational age at birth	..... weeks + ..... days
Live birth	<input type="radio"/> Yes <input type="radio"/> No
Neonatal death	<input type="radio"/> No <input type="radio"/> Yes (intra-uterine death) <input type="radio"/> Yes, <24 hours postpartum <input type="radio"/> Yes, >24 hours postpartum
Gender	<input type="radio"/> Female <input type="radio"/> Male <input type="radio"/> 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 pH (venous)	
Umbilical cord blood base excess (venous)	
Birth weight	(grams)
Fracture	<input type="checkbox"/> None <input type="checkbox"/> Humerus <input type="checkbox"/> Clavicle <input type="checkbox"/> Other <input type="checkbox"/> Unknown
Erbs palsy	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Preterm birth (<37 weeks of gestation)	<input type="radio"/> No <input type="radio"/> Yes (iatrogenic) <input type="radio"/> Yes (spontaneous)
Neonatal congenital malformation: heart	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Neonatal congenital malformation: neural tube	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Neonatal congenital malformation: urogenital	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Neonatal congenital malformation: other	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
First neonatal glucose postpartum	(mmol/L)
Date of first neonatal glucose testing postpartum	(dd-mm-yyyy)
Time of first neonatal glucose testing postpartum	(hh:mm)

Second neonatal glucose value postpartum	(mmol/L)
Date of second neonatal glucose testing postpartum	(dd-mm-yyyy)
Time of second neonatal glucose testing postpartum	(hh:mm)
Third neonatal glucose value postpartum	(mmol/L)
Date of third neonatal glucose testing postpartum	(dd-mm-yyyy)
Time of third neonatal glucose testing postpartum	(hh:mm)
Fourth neonatal glucose value postpartum	(mmol/L)
Date of fourth neonatal glucose testing postpartum	(dd-mm-yyyy)
Time of fourth neonatal glucose testing postpartum	(hh:mm)
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 postpartum	(dd-mm-yyyy)
Time of sixth neonatal glucose testing postpartum	(hh:mm)
Any neonatal glucose value between 2.0-2.6mmol/L ( $\geq 2.0 < 2.7$ ) during in hospital admission?	<ul style="list-style-type: none"> <li><input type="radio"/> No</li> <li><input type="radio"/> Yes, one value between 2.0 and 2.6</li> <li><input type="radio"/> Yes, more than one value between 2.0 and 2.6</li> <li><input type="radio"/> Unknown</li> </ul>
Any neonatal glucose value $< 2.0$ mmol/L during hospital admission?	<ul style="list-style-type: none"> <li><input type="radio"/> No</li> <li><input type="radio"/> Yes, one value <math>&lt; 2.0</math></li> <li><input type="radio"/> Yes, more than one value <math>&lt; 2.0</math></li> <li><input type="radio"/> Unknown</li> </ul>
<b>Postpartum</b>	
Were mother or child admitted directly postpartum? (including postpartum observation of mother/child)	<ul style="list-style-type: none"> <li><input type="radio"/> No (mother and child went home directly after delivery)</li> <li><input type="radio"/> Yes, maternal admission only</li> <li><input type="radio"/> Yes, maternal and neonatal admission</li> <li><input type="radio"/> Yes, neonatal admission only</li> </ul>
Maternal: what was the reason for admission?	<ul style="list-style-type: none"> <li><input type="checkbox"/> Maternal observation/routine stay (for instance because of more blood loss than usual or post-caesarean)</li> <li><input type="checkbox"/> Neonatal observation (for instance because of blood glucose evaluation)</li> <li><input type="checkbox"/> Fluxus (HPP)</li> <li><input type="checkbox"/> Pregnancy induced hypertension</li> <li><input type="checkbox"/> Preeclampsia</li> <li><input type="checkbox"/> HELLP syndrome</li> <li><input type="checkbox"/> Glycemic dysregulation</li> <li><input type="checkbox"/> Thrombo-embolic event</li> </ul>

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

	<input type="radio"/> 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 postpartum?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
How many days of iv glucose infusion?	(days)
<b>Diabetes treatment</b>	
What treatment was the participant randomized to?	<input type="radio"/> Insulin <input type="radio"/> Oral hypoglycemic agents
Did the participant ever use: metformin	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
On which date did the participant start with metformin?	(dd-mm-yyyy)
On which date did the participant stop with metformin?	(dd-mm-yyyy)
Did the participant ever use: glibenclamide	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
On which date did the participant start with glibenclamide?	(dd-mm-yyyy)
On which date did the participant stop with glibenclamide?	(dd-mm-yyyy)
Did the participant ever use: insulin?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
On which date did the participant start with insulin? (If multiple types of insulin were used, use the start date of the first type of insulin)	(dd-mm-yyyy)
On which date did the participant stop with insulin? (If multiple types of insulin were used, use the start date of the first type of insulin)	(dd-mm-yyyy)
Glucose profile most recent before or at randomization: fasting value	(mmol/L)
Glucose profile most recent before or at randomization: after breakfast value	(mmol/L)
Glucose profile most recent before or at randomization: after lunch value	(mmol/L)
Glucose profile most recent before or at randomization: after dinner value	(mmol/L)
Most recent HbA1c value before or at randomization	(mmol/mol)
Date of most recent HbA1c value before or at randomization	(dd-mm-yyyy)
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)
<b>Additional tests</b>	
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)
<b>End of study</b>	
Was there a protocol violation?	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Did a Serious Adverse Event (SAE) occur during the study until 6 weeks postpartum? (If yes, please report the SAE to the sponsor)	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Did a Suspected Unexpected Serious Adverse Reaction (SUSAR) occur during the study until 6 weeks postpartum? (If yes, please report the SUSAR to the sponsor)	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Please specify if the subject completed the entire course of the study as specified in the study protocol or discontinued the study:	<input type="radio"/> Completed <input type="radio"/> Discontinued
If discontinued, please specify the most appropriate reason for early termination	<input type="radio"/> Subject violates one or more of the inclusion/exclusion criteria <input type="radio"/> Adverse event <input type="radio"/> Participant deceased <input type="radio"/> Participant lost to follow up <input type="radio"/> Participant withdrew consent to use personal data <input type="radio"/> Investigator's and/or physician's decision <input type="radio"/> Total study is early terminated <input type="radio"/> Other reason
Has the participant signed informed consent for follow-up?	<input type="radio"/> Yes <input type="radio"/> No
Has the participant provided contact information to allow follow-up?	<input type="radio"/> Yes <input type="radio"/> No