

Inclusion

Patient ID

Civil Registration Number (CPR-nr)

Birthcenter

- Aarhus
- Randers
- Kolding
- Aalborg

Parity

- nullipara
- multipara UDEN tidl. sectio
- multipara MED tidl.sectio

Indication

- Induction
- PROM (Premature Rupture of Membranes)

Treatment

- Placebo
- Syntocinon

Randomization number

Package number

Randomization date

Kodebruds initialer

Kodebruds tekst

Kodebruds dato

Contact information (for questionnaires)

e-mail adress

Participant characteristics and history

Parity

- 0 - nullipara
- 1 - primipara
- 2
- 3
- 4
- 5
- 6
- 7
- Other
- NA

(Choose the number corresponding to the parity of the participant prior to the current pregnancy and labour.)

If other, enter parity

(IN case of missing value enter 99)

Prior caesarean section

- Yes
- No
- NA

(State if the women have had a Caesarean section prior to the current delivery. If no data available choose NA)

Height

(Enter the height of participant in centimeter (cm). If missing value please state: 999)

Weight prior to current pregnancy

(Enter weight of the participant in kilograms (kg) without decimals prior to pregnancy. If missing value please state 999)

BMI

((calculation field))

Educational status

- No schooling/less than primary
- Primary
- Lower secondary
- Upper secondary
- Post secondary non-tertiary
- Short cycle tertiary
- Bachelor or equivalent
- Master or equivalent
- Doctoral or equivalent
- Other
- NA

(In case of missing value choose NA)

If Other, enter education

Etnicity

- Caucasian
- Asian
- Afro-Caribbean
- Oriental
- Other
- Unknown

(Choose one box to indicate the race of the participant)

If other, enter race

(In case of missing value enter NA)

Smoking status during pregnancy

- Ever
- Never
- NA

(If missing value please state: NA)

marital status

- single
- married
- co-habiting
- NA

(In case of missing value choose NA)

Estimated birth weight

(Enter the latest estimated birth weight in gram.
If no data available enter 9999)

Birth weight estimation method

- Ultrasound
- Clinical examination
- NA

(Enter how the birth weight estimate has been done. If missing value please choose NA)

Which medical condition(s) of the below listed did the woman suffer from during pregnancy and labour?

- Gestational Diabetes
 - Diabetes Mellitus 1
 - Diabetes Mellitus 2
 - Hypertension
 - Preeclampsia
 - Metabolic disease
 - Intrauterine Growth Restriction (IUGR)
 - Autoimmune disease
 - Depression (treated with Anti-depressives at time of labour)
 - None of the above
- (Enter all of the conditions listet above that the woman suffers from)

Gestational age at birth (number of whole weeks)

(Enter the number of gestational age in whole weeks of pregnancy, e.g. GA 37+5 is to be entered as 37. In case of missing value enter 99)

Gestational age at birth (number of days in incomleted week)

(Enter the number of days in incompleted week of gestational age. E.g. GA 37+5 is to be entered as 5. If missing value enter 99)

Gestational age in days

(Calculated field. Will be filled out automatically)

Prostaglandine prior to stimulation with oxytocin

- Yes
- No
- NA

(Enter whether the woman has received prostaglandine (misoprostol/Angusta) prior to stimulation with oxytocin. If data is missing choose NA)

Total dosage of prostaglandine

(Enter total dosage of prostaglandine administered in mikrogram. If missing value enter 999)

Balloon dilatation prior to stimulation with oxytocin

yes

No

NA

(Choose if a cook cervical ripening balloon catheter has been used for mechanical dilatation of the cervical canal prior to labour induction.
In case of missing value choose NA)

Start of labour (Stimulation protocol)

Admission date and time on the delivery ward

(If missing value enter 01-01-2001 00:00)

Primary indication for stimulation with oxytocin

- PROM (Premature Rupture Of Membranes)
- Diabetes
- Gravida Prolongata
- Hypertension/preeclampsia
- IUGR (IntraUterine fetal Growth Restriction)
- Maternal request
- BMI >35
- Oligohydramnios
- Cholestasis
- NA

(Choose the primary indication for stimulation with oxytocin. If data is missing choose NA)

Date and time for initiation of stimulation with oxytocin

(If missing value enter 01-01-2001 00:00)

Cervical dilatation in centimeters (cm) at initiation time of stimulation with oxytocin

(If missing value enter 9)

Rupture of membranes or amniotomy prior to stimulation with oxytocin

- Yes
- No
- NA

(If missing value choose NA)

Date and time for rupture of membranes

(If missing value enter 01-01-2001 00:00)

Description of amniotic fluid

- clear
- meconium stained
- NA

(If missing value choose NA)

Use of epidural analgesia

- Yes
- No
- NA

(If missing value choose NA)

Date and time for insertion of epidural analgesia

(In case of missing value 01-01-2001 00:00)

Total number of vaginal examinations during stimulation with oxytocin, prior to project medicine

- 1
- 2
- 3
- 4
- 5
- 6
- NA

(If missing value choose NA)

Pausion of oxytocin prior to commencement of project medicine

- Yes
- No
- NA

(If missing value choose NA)

Time for pausion

(If missing value enter 01-01-2001 00:00)

Reason for pausation of oxytocin

- Uterine hyperstimulation
 - Non-reassurent CTG
 - NA
- (If missing value enter NA)

Total given volumen oxytocin

(If missing value enter 9999)

Initiation date and time for project medicine

(If missing value enter 01-01-2001 00:00)

Cervical dilatation at initiation time for project medicine
in centimeters (cm)

(If missing value enter 99)

Project medicine discontinued earlier than guideline provides (prior to delivery of the placenta)

- Yes
 - No
 - NA
- (If missing value choose NA)

Time for early discontinuation of project medicine

(If missing value enter 01-01-2001 00:00)

Reason for early discontinuation of project medicine

- Uterine hyperstimulation
 - Non-reassurent CTG
 - Dystocia
 - Other
 - NA
- (If missing value please enter NA)

Resumption of project medicine

- Yes
 - No
 - NA
- (If missing value choose NA)

Time for resumption of the project medicine

(If missing value enter 01-01-2001 00:00)

End time for stimulation with project medicine

(If missing value enter 01-01-2001 00:00)

Duration of project medicine (minutes)

(calculated field. Will be filled out automatically)

Maximal dosage of project medicine (mL/hour)

(If missing value enter 999)

Duration of stimulation in total

(Calculated field. Will be filled out automatically)

Total given volumen projectmedicin (ml)

(If missing value enter 9999)

Violation of the project protocol?

- Yes
 - No
 - NA
- (If missing value choose NA)

Describe any violence of the trial protocol

BLINDING

Unconcealed allocation of participant to personnel

Yes

Reason for unconcealment

- maternal request
- physician request
- midwife request
- NA

(If missing value enter NA)

Course of labour 1

Uterine hypertonia (single contraction lasting > 2 minutes) prior to project medicine

Yes

No

NA

(DURING STIMULATION WITH OXYTOCIN If missing value choose NA)

Uterine hyperstimulation prior to project medicine?

Yes

No

NA

(DURING STIMULATION WITH OXYTOCIN If missing value choose NA)

Uterine hyperstimulation is when stimulation with oxytocin leads to >5 uterine contractions per 10 minutes, during a period of 30 minutes.

Worst CTG classification during stimulation with oxytocin prior to project medicine

Normal

Suspicious

Pathological

Preterminal

NA

(DURING STIMULATION WITH OXYTOCIN. If missing value choose NA)

Uterine hypertonia (single contraction lasting > 2 minutes) during project medicine

Yes

No

NA

(DURING STIMULATION WITH PROJECTMEDICINE. If missing value choose)

Uterine hyperstimulation during project medicine?

Yes

No

NA

(DURING STIMULATION WITH PROJECTMEDICINE. If missing value choose)

Uterine hyperstimulation is when stimulation with oxytocin leads to >5 uterine contractions per 10 minutes, during a period of 30 minutes.

Worst CTG classification during treatment with project medicine

Normal

Suspicious

Pathological

Preterminal

NA

(DURING STIMULATION WITH PROJECTMEDICINE.If missing value choose NA)

Fetal-scalp blood measurement(s) during labour

Yes

No

NA

(If missing value choose NA)

Total number of fetal-scalp blood measurements

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- NA

(If 2 measurements routinely are performed at the same time, this only counts as 1 scalp pH measure. If missing value choose NA)

Lowest measured fetal-scalp pH value

(Enter 9, if no measurement has been done)

Lowest measured fetal-scalp lactate value

(Enter 9, if no measurement has been done)

Course of labour 2

Date and time for initiation of second stage of labour

(Enter the time when dilatation of cervix is 10 cm. If missing value enter 01-01-2001 00:00)

Initiation date and time for the active pushing periode

(If missing value enter 01-01-2001 00:00)

Time and date of birth

(If missing value enter 01-01-2001 00:00)

Duration of labour (minutes)
(stimulation with oxytocin until birth)

(Calculated field. Will be filled out automatically)

Date and time for discontinuation of stimulation
(projectmedicin or oxytocin)

(If missing value enter 01-01-2001 00:00)

If project medicine replaced with open labelled oxytocin:

(If missing value or non given: enter 99999)

Total volumen of oxytocin given

liveborn

Yes

No

NA

(If missing value choose NA)

Date and time for intrauterine death

(If missing value enter 01-01-2001 00:00)

Mode of delivery

Vaginal

Vacuum extraction

Cesarean

Forceps

NA

(If missing value choose NA)

Indication for instrumental or caesarean delivery

Asphyxia

Tired mom

dystocia

suspicion of uterine rupture

suspicion of chorioamnionitis

other

NA

(If missing value choose NA)

Describe other

Urgency of Ceasarean section

Grade 1 (Acute: immediate delivery)

Grade 2 (Delivery within 30 minutes from decision time)

Grade 3 (Delivery within 60 minutes from decision time)

NA

(Choose one of the choices above. If missing value please choose NA)

Cervical dilatation in centimeters (cm) at time of ceasarean section

(If missing value state 99)

Uterine rupture

Yes

No

NA

(If missing value please choose NA)

Intrapartum fever

Yes

No

NA

(In case of missing value choose NA)

Time for registration of intrapartum fever

(In case of missing value enter 01-01-2001 00:00)

Postpartum period

Did the woman incur a perineal tear

Yes

No

NA

(In case of missing value choose NA)

Degree of perineal tear:

Grade 1

Grade 2

Grade 3a

Grade 3b

Grade 4

NA

(If missing value choose NA)

Grade 1 (include only perineum)

Grade 2 (include also perineal muscle)

Grade 3a (include < 50% of sphincter ani)

Grade 3 b (include > 50% of sphincter ani)

Grade 4 (include sphincter ani and mucosa of rectum)

Was the placenta removed manually?

Yes

No

NA

(In case of missing value choose NA)

Volumen in mililiters (ml) of blood loss during delivery and the first 24 hours postpartum

(In case of missing value state 9999)

Given treatment for postpartum hemorrhage

Bimanual uterine massage

Medical

Bakri-ballon

B lynch

Bloodtransfusion

Profylactic Syntocinon (intramuscular injection)

other

No treatment needed/given

NA

(State the given treatment for atonia)

Describe other

Did urinary retention postpartum occur?

Yes

No

NA

(In case of missing value choose NA)

Defined by:

1.No spontaneously urination 6 hours postpartum if vaginal delivery

2. No spontaneously urination 6 hours after removal of CAD (catheter à demeure) if caesarean delivery

Treatment for urinary retention

Intermittent Catheterisation with disposable catheter

Catheter à demeure

NA

(If missing value choose NA)

Time for treatment for urinary retention

(If missing value enter 01-01-2001 00:00)

Antibiotic treatment due to puerperal infection

Yes

No

NA

(If missing value choose NA)

Date and time for discharge of the woman

(If missing value enter 01-01-2001 00:00)

Duration of admission

(Calculated field. Will be filled out automatically)

Readmission within the first week postpartum

Yes

No

NA

(In case of missing value choose NA)

Readmission due to

Suspected infection

Endometritis proven with culture

Urinary tract infection treated with antibiotics

Wound infection treated with antibiotics

Bowel obstruction

Pneumonia

Trombo-embolic complications

Eclampsia

HELLP

Admission due to child, no maternal reason

Other

NA

(If missing value choose NA)

Serious Adverse Events

Maternal cardiac arrest during labour

Yes

No

N/A

(In case of missing value choose NA)

Maternal amniotic fluid emboli

Yes

No

N/A

(If missing value enter NA)

Maternal thromboembolic event

Yes

No

NA

(In case of missing value choose NA)

Maternal Pulmonary edema

Yes

No

N/A

(In case of missing value choose NA)

Neonate + breastfeeding

Civil registration number (CPR nr) of newborn

(10 numbers without using hyphen or space)

Birth weight in gram

(In case of missing value enter 9999)

Apgar score at 1 minute

(If missing value enter 99)

Apgar score at 5 minutes

(If missing value enter 99)

Apgar score at 10 minutes

(If missing value enter 99)

Umbilical cord measurements

Umbilical arterial blood pH

(If missing value enter 99)

Umbilical arterial blood SBe (Standard Base excess)

(If missing value enter 99)

Date and time of birth of placenta

(If missing value enter 01-01-2001 00:00)

Duration between birth of neonate and birth of placenta

(Calculated field. Will be filled out automatically)

Neonate licking within the first 2 hours post partum

 Yes No NA

(In case of missing value please choose NA)

Neonate sucking within the first 2 hours postpartum

 Yes No NA

(In case of missing value choose NA)

Nutrition at discharge

 Exclusive breastfeeding Not exclusive breastfeeding NA

(In case of missing value choose NA)

Neonatal resuscitation within the first 10 minutes postpartum

 Yes No NA

(In case of missing value please choose NA)

Was the newborn ventilated within the first hour postpartum

 Yes No NA

(In case of missing value choose NA)

Did the newborn receive CPAP (Continuous Pulmonary Airway pressure) treatment during the first 24 hours postpartum?

- Yes
 No
 NA
(If missing value choose NA)

Intubation of the neonate within the first 24 hours postpartum

- Yes
 No
 NA
(If missing value choose NA)

Neonatal death within 7 days postpartum

- Yes
 No
 NA
(If missing value choose NA)

Date and time of death

(Ved missing value angiv 01-01-2001 00:00)

Was the newborn admitted to Neonatal Intensive Care Unit (NICU) within the first 24 hours

- Yes
 No
 NA
(If missing value choose NA)

ICD 10 codes (diagnosis-code) during admission at the Neonatal Intensive Care Unit (NICU)

(Enter the codes registered in the medical record of the newborn during the admission in NICU. If missing value enter NA)

Highest bilirubin-value measured

(If missing value enter 9999)

Enter the time for bilirubin measurement

(If missing value enter 01-01-2001 00:00)

Did the newborn receive therapy due to hyperbilirubinaemia

- Yes
 No
 NA
(If missing value please choose NA)

Long term maternal: Breastfeeding

Exclusive breastfeeding 17 weeks

Yes

No

NA

(Data from Børnedatabasen. In case of missing value enter NA)

Din fødselsoplevelse

Et af målene for Condisox-projektet er en positiv fødselsoplevelse for kvinder, som modtager ve-stimulerende drop.

Formlet med dette spørgeskema er at undersøge, hvordan du oplevede fødslen.

Vi har valgt at anvende et internationalt anerkendt spørgeskema (CEQ- Childbirth Experience Questionnaire).

Dine svar er vigtige for vores projekt og for kvinder som i fremtiden skal modtage vestimulerende drop. Derfor vil vi bede dig svare på alle spørgsmål. Nogle af spørgsmålene passer måske ikke helt på dig. Vi vil gerne have, du vælger de svar, der passer så godt som muligt på dig og din fødselsoplevelse.

Det tager ca 7 minutter at udfylde spørgeskemaet.

133) Fødslen forløb som jeg havde forestillet mig.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

134) Jeg følte mig stærk under fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

135) Jeg følte mig bange under fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

136) Jeg følte mig i stand til at gennemføre fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

137) Jeg var træt under fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

138) Jeg var glad under fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

139) Jeg har mange positive minder fra fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

140) Jeg har mange negative minder fra fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

141) En del af minderne fra fødslen kan få mig til at føle mig nedtrykt.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

142) Jeg følte, at jeg havde mulighed for at påvirke, om jeg skulle være oppe og røre mig eller ligge ned.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

143) Jeg følte, at jeg havde mulighed for at påvirke fødselsstillingen

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

144) Jeg følte, at jeg havde mulighed for at påvirke valg af smertelindring.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

145) Jordemoderen brugte tilstrækkelig tid på mig.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

146) Jordemoderen brugte tilstrækkelig tid på min partner.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

147) Jordemoderen informerede om, hvad der skete under fødslen.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

148) Jordemoderen forstod mine behov.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

149) Jeg følte, at jordemoderen behandlede mig godt.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

150) Mit indtryk af sygehushpersonalets faglige kompetence gjorde mig tryg.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

151) Jeg følte, at jeg håndterede situationen godt.

- Passer helt
- Passer delvist
- Passer ikke særlig godt
- Passer slet ikke
- Ønsker ikke at svare
(Sæt kryds i én boks)

152) Hvor smertefuld oplevede du generelt fødslen?

- Ingen smerte
 -
 -
 -
 -
 -
 -
 -
 -
 - Værst tænkelige smerte
 - Ønsker ikke at svare

153) Hvor meget kontrol følte du, at du generelt havde under fødslen?

- Ingen kontrol
-
-
-
-
-
-
- Fuldstændig kontrol
- Ønsker ikke at svare
(Sæt kryds i det felt på skalaen, som passer bedst på din oplevelse)

154) Når du tænker tilbage på fødslen, hvor tryg
følte du dig generelt?

- Slet ikke tryg

 Fuldstændig tryg
 Ønsker ikke at svare
(Sæt kryds i det felt på skalaen, som passer
bedst på din oplevelse)

155) Egne kommentarer

(Her har du mulighed for at tilføje dine egne
kommentarer)