

Case number: -

# Quadruple P

## Confidential Case report form

Comparing the effectiveness of vaginal progesterone and cervical pessary in the prevention of preterm birth in women with singleton and twin pregnancies with a short cervix: a multicentre randomised trial.

Case number: -  
Patient initials:

*This is a CRF handout for the purpose of support for the Quadruple P website.*

CRF data entry, information and randomisation:

<http://www.studies-obsgyn.nl/>

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Principal investigator: E. Pajkrt, gynaecologist

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**TO BE FILLED OUT AT STUDY ENTRY:****1. General****1.1. General information**Clinic: 

- 02 = Academisch Medisch Centrum, Amsterdam
- 34 = Amphia Ziekenhuis, Breda
- 05 = Atrium Medisch Centrum, Heerlen
- 57 = Bethesda Ziekenhuis, Hoogeveen
- 58 = BovenIJ Ziekenhuis, Amsterdam
- 21 = Bronovo Ziekenhuis, Den Haag
- 50 = Canisius Wilhelmina Ziekenhuis, Nijmegen
- 16 = Catharina Ziekenhuis, Eindhoven
- 14 = Deventer Ziekenhuis, Deventer
- 32 = Diaconessenhuis, Utrecht
- 24 = Elkerliek ziekenhuis, Helmond
- 47 = Erasmus Medisch Centrum, Rotterdam
- 51 = Flevoziekenhuis, Almere
- 15 = Gelre Ziekenhuis, Apeldoorn
- 35 = Ikazia Ziekenhuis, Rotterdam
- 45 = Isala Klinieken, Zwolle
- 20 = Jeroen Bosch Ziekenhuis, 's Hertogenbosch
- 70 = Kennemer Gasthuis, Haarlem
- 01 = Leids Universitair Medisch Centrum, Leiden
- 04 = Maastricht Universitair Medisch Centrum, Maastricht
- 08 = Martini Ziekenhuis, Groningen
- 07 = Máxima Medisch Centrum, Veldhoven
- 33 = Meander Medisch Centrum, Amersfoort
- 29 = Medisch Centrum Alkmaar
- 27 = Medisch Centrum Leeuwarden
- 36 = Medisch Spectrum Twente, Enschede
- 78 = Nij Smellinghe ziekenhuis, Drachten
- 09 = Onze Lieve Vrouwe Gasthuis, Amsterdam
- 48 = Orbis Medisch Centrum, Sittard-Geleen
- 43 = Radboud Universitair Medisch Centrum, Nijmegen
- 81 = Rijnland - Alphen ad Rijn / Leiderdorp
- 39 = Rijnstate, Arnhem
- 85 = Ruwaard van Putten ziekenhuis - Spijkenisse
- 37 = Scheper Ziekenhuis, Emmen
- 11 = Sint Antonius Ziekenhuis, Utrecht
- 13 = Sint Elisabeth Ziekenhuis, Tilburg
- 40 = Sint Lucas Andreas Ziekenhuis, Amsterdam
- 30 = Spaarne Ziekenhuis, Hoofddorp
- 65 = Tergooiziekenhuis, Blaricum
- 06 = TweeSteden ziekenhuis, Tilburg
- 03 = Universitair Medisch Centrum Groningen
- 12 = Universitair Medisch Centrum Utrecht
- 26 = VieCuri Medisch Centrum voor Noord-Limburg, Venlo
- 28 = Zaans Medisch Centrum – Zaandam
- 94 = Ziekenhuisgroep Twente, Almelo

Case number: -

**Composition of pregnancy:**

- Singleton
- Twin

Case number:  -  (clinic - case)

Date of birth: -- (dd-mm-yy)

Estimated due date -- (dd-mm-yy)

**1.2. Inclusion criteria**

Inclusion criteria*		No	Yes
1.	Singleton pregnancy and cervical length of 35 mm or less ( $\leq 35$ mm) at 18+0 to 21+6 weeks	<input type="radio"/>	<input type="radio"/>
	OR		
	Twin pregnancy and cervical length of 38 mm or less ( $\leq 38$ mm) at 16+0 to 21+6 weeks		

**1.3. Exclusion criteria**

Maternal/Fetal Exclusion criteria		No	Yes
		<input type="radio"/>	<input type="radio"/>
	Cervical cerclage in this pregnancy	<input type="radio"/>	<input type="radio"/>
	Maternal age less than 18 years	<input type="radio"/>	<input type="radio"/>
	Cervical dilatation $\geq 3$ cm	<input type="radio"/>	<input type="radio"/>
	Identified major congenital abnormalities #	<input type="radio"/>	<input type="radio"/>
	Death of one or both of the foetuses	<input type="radio"/>	<input type="radio"/>
	History of preterm singleton birth before 34 weeks of gestation	<input type="radio"/>	<input type="radio"/>
	Participation Quadruple P study in previous pregnancy	<input type="radio"/>	<input type="radio"/>

# Major fetal abnormalities are defined as those that are lethal or require intensive prenatal care or postnatal surgery.

**2. Randomisation**

**Randomisation result:**

Case number: -

- Pessary
- Progesteron




No randomization (observational cohort)

|  
If consent for observational cohort signed:

Estimated due date -- (dd-mm-yy)

*Child*

Live birth

- Yes
- Termination of pregnancy 
- No, deceased before labor 
- No, deceased during labor 

Date of birth or date of diagnosis of death -- (dd-mm-yy)

Gender:  Boy  Girl

Birth weight  (kg)

Did patient receive progesterone?  yes  no |  
|  
If yes start date:  
stop date:

Did patient receive a pessary?  yes  no |  
|  
If yes start date:  
stop date:

Has there been complication related to the pessary or progesterone?  
If yes please specify:.....

**TO BE FILLED OUT AFTER RANDOMISATION:**

**3. Demographics**

**Ethnicity:**

- Caucasian
- Indian/ Pakistani/ Bangladesi
- Afro-Caribbean (Antillen, Suriname – creool)
- Hindu, Caribbean (Suriname – hindu)
- African (sub-Sahara)
- Middle-East + North Africa (Turkish and Moroccan)
- Asian
- Other
- Unknown

**Highest finished education:**

- Primary school (basisschool)
- Secondary school (havo, VWO, gymnasium)
- Lower professional school (VMBO)
- Medium professional school (MBO)
- Higher professional school (HBO – post HBO)
- University (WO)
- Unknown

**4. Medical history****Diseases:**

Diabetes Mellitus	<input type="radio"/> no	<input type="radio"/> yes
Hypertension	<input type="radio"/> no	<input type="radio"/> yes
Depression	<input type="radio"/> no	<input type="radio"/> yes
Renal insufficiency	<input type="radio"/> no	<input type="radio"/> yes
Inflammatory bowel disease	<input type="radio"/> no	<input type="radio"/> yes
Thrombophilia	<input type="radio"/> no	<input type="radio"/> yes
Thyroid disease	<input type="radio"/> no	<input type="radio"/> yes

**Risk factors for preterm delivery:**

Conisation/ LETTZ	<input type="radio"/> no	<input type="radio"/> yes	<input type="radio"/> unknown
Uterus anomaly	<input type="radio"/> no	<input type="radio"/> yes	<input type="radio"/> unknown
Known uterine surgery	<input type="radio"/> no	<input type="radio"/> yes	<input type="radio"/> unknown
Smoking	<input type="radio"/> no	<input type="radio"/> yes	<input type="radio"/> quitted in first trimester
	<input type="radio"/> unknown		
		If yes or quitted,	
		Amount: <input type="radio"/> ≤ 10 sig/day	
		<input type="radio"/> > 10 sig/day	
		<input type="radio"/> unknown	
Treated urinary tract infections in past year	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> >1
			<input type="radio"/> unknown

## 5. Obstetric history

Gravidity  ; Parity ; Miscarriage/abortion/ectopic pregnancy\*   
 \* < 16 weeks

Was there any curettage?  
 no    yes    unknown

Missing value (unknown) = -1

If the obstetric history contains a preterm delivery < 34 weeks, then the patient cannot be randomized.

0 = spontaneously  
 1 = vacuum  
 2 = forcipal extraction  
 3 = caesarian (secondary)  
 -1 = unknown

0 = spontaneously  
 1 = induction  
 2 = caesarian (primary)  
 3 = curettage  
 -1 = unknown

GA: weeks + days

XX/'XX

Birth weight 50-6000 gram

	Date of birth Month/Year	GA	Start	Route	Birth weight	If twin: Birth Weight Baby 2
1.	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> + <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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11.	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> + <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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14.	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> + <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>



**6. Current pregnancy****6.1. Start of pregnancy**

Mode of conception:

- Spontaneous
- IUI
- Ovulation induction
- IVF
- ICSI

Height:  cm (140-210)Weight before pregnancy  kg (40-250)**6.2. Laboratory results at study entry****GBS carrier**GBS carrier (known prior to pregnancy)  no  yes  unknown**6.3. Fetal data at study entry**

Composition of pregnancy:

- Singleton
- Twin, diamniotic, dichrionic
- Twin, diamniotic, monochorionic
- Twin, monoamniotic, monochrionic
- Twin, chorionicity unknown
- Triplet, triamniotic, trichrionic
- Triplet, dichorionic diamniotic
- Triplet, dichorionic triamniotic
- Triplet, monochorionic, triamniotic
- Triplet, monochorionic, diamniotic
- Triplet, monochorionic, monoamniotic
- Triplet, chorionicity unknown

**6.4. Transvaginal Ultrasound**

Case number: -

**Transvaginal ultrasound at admission:**

Date of cervical length measurement

-- (dd-mm-yy)

Cervical length at randomisation

mm (≥5 to 38)

Funneling

no    yes    unknown

Sludge

no    yes    unknown

**7. Intervention****7.1. Pessary or progesterone**

Randomisation result

 pessary progesterone**When randomized to pessary**

Did patient receive a pessary:

 no  yes

|

 cervical length too small pessary size not in stock woman refused pessary placement delivered before placement patient preferred progesterone doctor preferred progesterone unknown

Date of placing pessary

-- (dd-mm-yy)

Size pessary

 Small

65x25x32

 Medium (standard)

70x25x32

 Large

70x25x35

 unknown/other

When was the pessary removed?

Date:

 -  -  (dd-mm-yy)

Why was the pessary removed?

 GA > 36 weeks vaginal pain excessive discharge (P)PROM vaginal blood loss contractions/labor Pessary fell out Require delivery for other reasons patient changed to progesterone

If the pessary was removed, was it replaced?

 no yes unknown

If yes,

Date:  -  -  (dd-mm-yy)

Case number: -

Was the second pessary removed?

no  yes  unknown

- |
- GA > 36 weeks
  - vaginal pain
  - excessive discharge
  - (P)PROM
  - vaginal blood loss
  - contractions/labor
  - Pessary fell out
  - Require delivery for other reasons
  - patient changed to progesterone

Final date of removal pessary:

Date: -- (dd-mm-yy)

**When randomized to progesterone**

Did patient start with progesterone:  no  yes

- |
- woman refused use of progesterone
  - delivered before starting
  - patient preferred a pessary
  - doctor preferred a pessary
  - unknown

Date of starting progesterone therapy

-- (dd-mm-yy)

Type of progesterone:

- Vaginal suppository
- Gel
- Injection

Dose of progesterone:

- 80 mg
- 100 mg
- 200 mg
- 250 mg
- other/unknown

Case number: -

When did the patient stop with the progesterone therapy?

Date:  -  -  (dd-mm-yy) #

**# actual stopdate**  **unknown** Why did the patient stop with progesterone therapy?

- GA > 36 weeks
- vaginal pain
- discharge
- PPROM
- vaginal blood loss
- contractions/labor
- Require delivery for other reasons
- patient changed to a pessary
- other

If the therapy was stopped, was it restarted?

no  yes  unknown

If yes,

Date:  -  -  (dd-mm-yy)

Did the patient stop again with the progesterone therapy?

no  yes  unknown

- GA > 36 weeks
- vaginal pain
- excessive discharge
- (P)PROM
- vaginal blood loss
- contractions/labor
- Require delivery for other reasons
  
- patient changed to a pessary
- other

**How many capsules did the patient receive?**

0  70  140  unknown

**How many capsules were send back by the patient?**

none  ( amount)

Final date of stop progesterone therapy.

Date:  -  -  (dd-mm-yy)

Case number: -

### 8.1 Pregnancy complications after randomization

Treated genital tract infection       no       yes       unknown

Treated urinary tract infection       no       yes       unknown

Ruptured membranes <36 weeks       no       yes       unknown

|  
If yes, Date:  
 -  -  (dd-mm-yy)

Excessive vaginal discharge       no       yes       unknown

Vaginal blood loss  
*not related to placing pessary*       no       yes       unknown

Pelvic pain  
*not related to placing pessary*       no       yes       unknown

#### Chorioamnionitis

*Requires 2 of the following: fever, fundal tenderness, maternal tachycardia, fetal tachycardia, foul-smelling amniotic fluid*

no       yes       unknown

#### Twin Twin Transfusion syndrome

no       yes       unknown

**8.2 Admissions after randomization**

**Fill in the details for number of admissions:**

- 1= Ward
- 2= Medium care
- 3= Intensive care
- 4= home monitoring

- 1= Threatened preterm birth
- 2= PE
- 3= IUGR
- 4= Complication of placing pessary
- 5= Decreased fetal movement
- 6= Labor/induction
- 7= Vaginal bleeding
- 8= Other
- 10=unknown

Admission number	Date of admission to hospital (dd-mm-yy)	Date of discharge from hospital (dd-mm-yy)	Type of admission	Primary indication for admission
1	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>		
2	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>		
3	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>		
4	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>		
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6	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>		
7	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>		
8	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>		





Case number: -

Transverse

Did mother require antibiotics in labor for treatment of suspected infection (not prophylaxis)?  no  yes  unknown

Did mother receive tocolysis?  no  yes  unknown

Did mother received corticosteroids?  no  yes  unknown

Did mother receive magnesium sulfate?  no  yes  unknown

"Did the patient ever receive a cerclage?  no  yes date

In case of cerclage, date removal stitches -- (dd-mm-yy)

Treated postpartum endometritis or pelvic infection?  no  yes

## 10. Neonatal data post-partum

*Child 1*

Live birth  Yes  
 No, termination of pregnancy  
 No, deceased before labor  
 No, deceased during labor

 Date of diagnosis of death -- (dd-mm-yy)

Gender:  Boy  Girl

Apgar-scores:

1 min  (0-10)

5 min  (0-10)

Weight at birth  gr. (0 - 6000)

Umbilical cord measurements: (pH: 6.00-7.70; BE: -30.0-+10.0; unknown: -1)

Art. pH .  Art. BE .

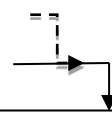
Ven. pH .  Ven. BE .

Case number: -

Child 2:

Live birth

- Yes
- Termination of pregnancy
- No, deceased before labor
- No, deceased during labor



Date of diagnosis of death -- (dd-mm-yy)

Gender:

- Boy
- Girl

Apgar-scores:

1 min  (0-10)

5 min  (0-10)

Weight at birth

gr. (0 - 6000)

Umbilical cord measurements: (pH: 6.00-7.70; BE: -30.0-+10.0; unknown: -1)

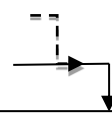
Art. pH . Art. BE .

Ven. pH . Ven. BE .

Child 3:

Live birth

- Yes
- Termination of pregnancy
- No, deceased before labor
- No, deceased during labor



Date of diagnosis of death -- (dd-mm-yy)

Gender:

- Boy
- Girl

Apgar-scores:

1 min  (0-10)

5 min  (0-10)

Weight at birth

gr. (0 - 6000)

Umbilical cord measurements: (pH: 6.00-7.70; BE: -30.0-+10.0; unknown: -1)

Art. pH . Art. BE .

Ven. pH . Ven. BE .



Case number: -

Maternal death  No  Yes

|

date <input type="text"/> - <input type="text"/> - <input type="text"/> (dd-mm-yy)
--

Date of final discharge to home -- (dd-mm-yy)

<b>11.2 Neonatal Admission</b>
--------------------------------

**Admission #1**

Type of admission  Ward  
 Medium care  
 Neonatal intensive care unit

Discharge to  Home Complete "Date of final discharge to home"  
 Other ward-----> Transfer date -- (dd-mm-yy)  
 Other hospital\_!

**Admission #2**

Type of admission  Ward  
 Medium care  
 Neonatal intensive care unit

Discharge to  Home Complete "Date of final discharge to home"  
 Other ward-----> Transfer date -- (dd-mm-yy)  
 Other hospital\_!

**Admission #3**

Type of admission  Ward  
 Medium care  
 Neonatal intensive care unit

Discharge to  Home Complete "Date of final discharge to home"  
 Other ward-----> Transfer date -- (dd-mm-yy)  
 Other hospital\_!

Neonatal death before discharge home?  No  Yes

|

date <input type="text"/> - <input type="text"/> - <input type="text"/> (dd-mm-yy)
time <input type="text"/>

Date of final discharge to home -- (dd-mm-yy)

Case number: -

**12. Neonatal diagnosis**

*Diagnosis as reported in the neonatal discharge letter of the pediatrician, all reported until 10 weeks after expected due date.*

Chronic lung disease	<input type="radio"/> No	<input type="radio"/> Yes, no therapy <input type="radio"/> Yes, only intubation/CPAP <input type="radio"/> Yes, intubation/CPAP and surfactant
Necrotizing Enterocolitis (NEC)* <sup>2</sup>	<input type="radio"/> No	<input type="radio"/> Stage 1 <input type="radio"/> Stage 2 <input type="radio"/> Stage 3
Intracerebral haemorrhage (IVH)* <sup>3</sup>	<input type="radio"/> No	<input type="radio"/> Grade 1 <input type="radio"/> Grade 2 <input type="radio"/> Grade 3 <input type="radio"/> Grade 4 <input type="radio"/> Grade unknown
Periventricular leukomalacia (PVL)* <sup>4</sup>	<input type="radio"/> No	<input type="radio"/> Grade 1 <input type="radio"/> Grade 2 <input type="radio"/> Grade 3 <input type="radio"/> Grade 4 <input type="radio"/> Grade unknown
Retinopathy of Prematurity (ROP)	<input type="radio"/> No	<input type="radio"/> Yes, no therapy <input type="radio"/> Yes, conservative treatment (e.g. oxygen or medical therapy) <input type="radio"/> Yes, requiring surgery
Patent ductus arteriosus (PDA)	<input type="radio"/> No	<input type="radio"/> Yes, no therapy <input type="radio"/> Yes, conservative treatment (e.g. medical therapy) <input type="radio"/> Yes, requiring surgery
Treated seizures	<input type="radio"/> No	<input type="radio"/> Yes
Early neonatal sepsis (<72 hours)* <sup>5</sup>	<input type="radio"/> No	<input type="radio"/> Suspected <input type="radio"/> Proven with positive culture
Late neonatal sepsis (>72 hours)* <sup>6</sup>	<input type="radio"/> No	<input type="radio"/> Suspected <input type="radio"/> Proven with positive culture
Neonatal meningitis	<input type="radio"/> No	<input type="radio"/> Suspected <input type="radio"/> Proven with positive culture
Other		Specify.....

\* Defined as:

- infants with oxygen dependency at either 28 days of life or 36 weeks' gestation
- Necrotizing Enterocolitis (NEC) > stage 1: the presence of the characteristic clinical features of abdominal distention, with or without rectal bleeding, and abdominal radiographic finding associated with pneumatosis intestinalis (this last finding is an abnormal gas pattern with dilated loops consistent with ileus). Staging according to Bell stages
- intracerebral haemorrhage grade III or IV: IVH with ventricular dilation or parenchymal extension, confirmed by MRI, sonogram or CT scan
- Periventricular lucency in the white matter.
- If prior to or at 72 hours of life the infant had an infection marked by positive blood, CSF, or urine (catheterized or suprapubic) cultures with or without suspicious clinical findings of infection on physical examination.
- If after 72 hours of life the infant had an infection marked by positive blood, CSF, or urine (catheterized or suprapubic) cultures with or without suspicious clinical findings of infection on physical examination.  
OR  
If there is clinical evidence of cardiovascular collapse or an unequivocal X-ray confirming infection and often cardiovascular decomposition

Case number: -

### 13. Serious Adverse Event

In this pregnancy has there been a Serious Adverse Event (SAE)?

no

yes

|

Perinatal death

Maternal death

Maternal hospitalization or prolongation of existing inpatients' hospitalization (not related to delivery or threatened preterm birth)

In this pregnancy has there been an Adverse Event (AE)?

no

yes

|

Preterm labor (before AD 34<sup>0/7</sup>)

Severe neonatal morbidity (NICU admission)

Necrotic cervix due to pessary

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**END OF Case Report Form**  
**THANK YOU FOR FILLING OUT THIS FORM**

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