# Preventing preterm birth in Chinese women with a short cervix in singleton pregnancies

| Submission date   | Recruitment status       | <ul><li>Prospectively registered</li></ul>    |
|-------------------|--------------------------|---|
| 10/04/2012        | No longer recruiting     | Protocol                                      |
| Registration date | Overall study status     | Statistical analysis plan                     |
| 16/04/2012        | Completed                | Results                                       |
| Last Edited       | Condition category       | Individual participant data                   |
| 19/09/2014        | Pregnancy and Childbirth | <ul><li>Record updated in last year</li></ul> |

### Plain English summary of protocol

Background and study aims

The chance that a woman will go into labour and deliver before 34 weeks is about 1%, but in women with a short cervix the chance of premature birth before 34 weeks increases to 4 to 40%. The majority of babies born prematurely survive and develop normally. However, babies born before 34 weeks have a higher chance of dying soon after birth or becoming disabled than babies born at term. There is some evidence that in singleton pregnancies with a previous premature birth or a short cervix, the chance of premature birth may be reduced by using progesterone or performing cervical cerclage. However, there is no single best effective intervention that has been proven to prolong pregnancy in women at risk, and some forms of treatment like cervical cerclage may even impose risk to the mother and fetus. There is some evidence that in women at risk of preterm delivery, the use of a vaginal pessary reduces the chance of premature birth, but the evidence is weak and therefore this issue needs further investigation. The aim of this study is to determine the effect of a vaginal pessary on the incidence of preterm delivery in women with a short cervix.

### Who can participate?

Chinese women found to have a short cervix (less than 25 mm) with a singleton pregnancy.

#### What does the study involve?

You will be randomly allocated to one of two groups, either the expectant management group or the pessary group. Irrespective to which group you are allocated to, we will see you in our clinic every four weeks and carry out ultrasound scans to examine the baby and measure the length of your cervix.

### What are the possible benefits and risks of participating?

Previous studies using the pessary have shown no adverse effects on the baby. A few women may experience increased vaginal discharge but the pessary does not cause a vaginal infection. During your visits to the hospital we will ask you if you have developed any vaginal discharge. If you have such a discharge we will examine you to find out if you have an infection and treat you with the necessary antibiotics.

Where is the study run from?

The study is conducted by Department of Obstetrics and Gynaecology at the Chinese University of Hong Kong.

When is the study starting and how long is it expected to run for? The study ran from October 2008 to February 2011.

Who is funding the study? The primary study site is at Prince of Wales Hospital, Hong Kong.

Who is the main contact? Dr Annie Hui Tel: 2632 2211

# **Contact information**

### Type(s)

Scientific

#### Contact name

Dr Shuk Yi Annie Hui

#### Contact details

1E, Department of OG Prince of Wales Hospital Shatin, N.T.

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Hong Kong

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# Additional identifiers

Protocol serial number

CRE-2008.375-T

# Study information

### Scientific Title

Cerclage pessary for preventing preterm birth in Chinese women with a short cervix in singleton pregnancies: a randomized controlled trial

### **Study objectives**

Determine the effect of cerclage pessary on the incidence of spontaneous delivery between randomization and 34 weeks in women with a short cervix less than 25 mm in a singleton pregnancy

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Joint Chinese University of Hong Kong - New Territories East Cluster (CUHK-NTEC) Clinical Research Ethics Committee (Hong Kong)

### Study design

Randomized controlled single-centre trial

### Primary study design

Interventional

### Study type(s)

Prevention

### Health condition(s) or problem(s) studied

Cervical insufficiency

#### **Interventions**

Women invited to participate were randomized into two arms: control group or pessary group. Randomization was performed using a computer-generated sequence and the allocation results were concealed in sequentially numbered, identical, opaque, sealed envelopes and kept away from the clinic where patients were being assessed. The treatment allocation would only be revealed to the obstetrician in charge after the patient was assessed to be eligible and consented to the trial.

Follow-up visits for ultrasound assessment of fetal growth and cervical length were carried out every four weeks till 34 weeks of gestation. If after 26 weeks the cervical length was less than 10 mm, steroids (four doses of intramuscular injections of dexamethasone 6 mg 12 hours apart) were given. High vaginal swabs were repeated during each follow-up visit to look for any infection.

# Intervention Type

Other

#### Phase

Not Applicable

### Primary outcome(s)

Preterm rate before 34 weeks

### Key secondary outcome(s))

Perinatal morbidities and mortality

### Completion date

28/02/2011

# **Eligibility**

### Key inclusion criteria

Women with singleton viable pregnancy undergoing routine morphology ultrasonography at 18 24 weeks found to have a cervix less than 25 mm

### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

#### Sex

Female

### Key exclusion criteria

- 1. Multiple pregnancies
- 2. Major fetal abnormalities defined as those that are lethal or require prenatal or postnatal surgery
- 3. Severe intra-uterine growth restriction (IUGR)
- 4. Cervical dilatation, painful uterine contractions, history of ruptured membranes, or prophylactic surgical cerclage before randomization
- 5. Patients who are unconscious, severely ill, mentally handicapped or under the age of 16 years

### Date of first enrolment

01/10/2008

### Date of final enrolment

28/02/2011

# Locations

### Countries of recruitment

Hong Kong

# Study participating centre 1E, Department of OG

Hong Kong

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# Sponsor information

### Organisation

Prince of Wales Hospital (Hong Kong)

### **ROR**

https://ror.org/02827ca86

# Funder(s)

### Funder type

University/education

### Funder Name

Chinese University of Hong Kong (Hong Kong)

# **Results and Publications**

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes