ISRCTN18185477 https://doi.org/10.1186/ISRCTN18185477

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

Submission date
10/04/2012

Recruitment status
No longer recruiting

Registration date
16/04/2012

Overall study status
Completed

Last Edited
19/09/2014

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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.
-
Hong Kong
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Preterm rate before 34 weeks

Secondary outcome measures
Perinatal morbidities and mortality

Overall study start date
01/10/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
4000

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
-

Sponsor information

Organisation
Prince of Wales Hospital (Hong Kong)

Sponsor details
Shatin, N.T.
-
Hong Kong
-

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02827ca86

Funder(s)

Funder type
University/education

Funder Name
Chinese University of Hong Kong (Hong Kong)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration