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Preconceptional transvaginal cervicoisthmic cerclage versus transvaginal cervicoisthmic cerclage in pregnancy for the prevention of preterm delivery in women with cervical insufficiency

Submission date
25/11/2014

Recruitment status
No longer recruiting

Registration date
14/01/2015

Overall study status
Completed

Last Edited
04/03/2019

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 cervix is a narrow, tube-like, lower end of the uterus (womb) that then opens out into the vagina. During pregnancy secretions are produced that form a protective barrier called the mucus plug and it remains long, firm and closed until very late into the third trimester where it softens up again and becomes shorter (dilates) in preparation for labour. Cervical insufficiency is a condition where the cervix softens and dilates prematurely. It is a major cause of second-trimester miscarriage and premature birth. The transvaginal cervicoisthmic cerclage is an effective, minimal-invasive procedure where a band of strong thread is stitched around the cervix to reinforce it, helping to keep it closed and prolong the gestational age (i.e. the pregnancy) for cervical insufficiency patients. In previous research, we have compared how successful transvaginal cervicoisthmic cerclage is in preventing premature birth when the procedure is performed before pregnancy compared with during pregnancy. We found that the number of woman able to reach full-term pregnancy was greater in the group that underwent the procedure when already pregnant but there was no difference in the perinatal (late pregnancy and just after birth) survival rate or fetal weight between the two groups. Here, we want to compare the obstetric outcome of cerclage done before and during pregnancy.

Who can participate?
Woman with cervical insufficiency who have had at least 2 previous late inevitable abortion /spontaneous preterm delivery, or traumatic/surgical damage of cervix. All participants should be younger than 35 years old, and able to conceive.

What does the study involve?
Patients are randomly allocated into two groups, and the modified transvaginal cervicoisthmic cerclage is then performed by the same surgeon, helped by one or two physicians.
Group 1: Undergo the modified transvaginal cervicoisthmic cerclage before pregnancy.

Group 2: Undergo the modified transvaginal cervicoisthmic cerclage during the first 12-14 weeks of pregnancy.

What are the possible benefits and risks of participating?
The transvaginal cervicoisthmic cerclage should prolong the gestational age for all patients. Any side effects are associated with the surgical procedure and include bleeding, pain, infection and early failure.

Where is the study run from?
Sir Run Run Shaw Hospital (China)

When is the study starting and how long is it expected to run for?
December 2014 to December 2020

Who is funding the study?
Zhejiang Province (Health high-level innovative talents training) (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Preconceptional transvaginal cervicoisthmic cerclage versus transvaginal cervicoisthmic cerclage in pregnancy for the prevention of preterm delivery in women with cervical insufficiency: a randomized controlled study

Study objectives
Cervical insufficiency is a predominant factor implicated in the etiology of preterm birth or second-trimester fetal loss, and the transvaginal cervicoisthmic cerclage is an effective and minimal-invasive technique to prolong the gestational age for the cervical insufficiency patients. The aim of this study is to compare the efficacy of preterm delivery prevention between preconceptional cerclage and cerclage in pregnancy. The principal questions of the research are the delivery gestational age and the perinatal infant survival rate after transvaginal cervicoisthmic cerclage. We hypothesize the delivery gestational age in the pregnancy cerclage subgroup is longer than that in the perconceptional cerclage subgroup, but the perinatal infant survival rates are similar in two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical ethics committee, Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, 16 /03/2015

Study design
Single-centre prospective randomized controlled study

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cervical insufficiency

Interventions
The modified transvaginal cervicoisthmic cerclage was performed by the same surgeon, assisted with one or two physicians. The preconceptional cerclage was performed with general

anesthesia, and the cerclage in pregnancy was performed with epidural anesthesia. The prophylactic antibiotics were transfused to all patients, and magnesium sulfate was used during the cerclage for the pregnant patients.
Group 1: perform the modified transvaginal cervicoisthmic cerclage before pregnancy
Group 2: perform the modified transvaginal cervicoisthmic cerclage during pregnancy between 12 and 14 weeks of gestational age.
For the analyses of pregnancy outcome, only used the results of the first pregnancy after preconceptional cerclage and the recent pregnancy outcome for the cerclage in pregnancy. The information about the subsequent obstetric outcomes was collected by the telephone interviews.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. The perinatal survival rate
2. The delivery gestational age

Secondary outcome measures
1. Complications during pregnancy
2. The fetal weight

Overall study start date
01/12/2014

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/03/2019:
1. A history of at least 1 previous late inevitable abortion or spontaneous preterm delivery
2. Previous conization of the cervix or cervical laceration by assisted vaginal delivery, and the residual cervix is less than 25mm
3. All patients should be >=18 years and younger than 35 years old
4. All patients are able to conceive

Previous inclusion criteria:
1. A history of at least 2 previous late inevitable abortion or spontaneous preterm delivery
2. Previous conization of the cervix or cervical laceration by assisted vaginal delivery, and the residual cervix is less than 25mm
3. All patients should be >=18 years and younger than 35 years old
4. All patients are able to conceive

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Older than 35 years old
2. Patients with a successful or failed cerclage applied in a previous pregnancy
3. Patients with congenital uterine dysplasia: Mediastinum uterus, bicornuate uterus, rudimentary horn of uterus, et al.
4. Patients with protein C, protein S, or antithrombin III deficiency
5. Patients who are pregnant

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
China

Study participating centre
Department of Obstetrics and Gynecology
Sir Run Run Shaw Hospital
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Sponsor information

Organisation
Health Bureau of Zhejiang Province

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216# Qingchun Road
Hangzhou,Zhejiang
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310006

Sponsor type
Government

Website
http://www.zjwst.gov.cn/

Funder(s)

Funder type
Government

Funder Name
Zhejiang Province (Health high-level innovative talents training) (China)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request