The effectiveness of Cerclage for the reduction of extreme preterm birth and perinatal mortality in Twin pregnancies with a short cervix.

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To assess the effectiveness of a cerclage in women with a twin pregnancy with a midpregnancy short cervix compared to standard treatment (no cerclage) in the prevention of extreme preterm birth (PTB) < 28 weeks of GA.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON53843

Source
ToetsingOnline

Brief title
TWIN Cerlage study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Premature birth, Preterm birth, preterm deliveru

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonNW

Intervention

Keyword: Cervical cerclage, Preterm birth, Prevention, Twin pregnancy

Outcome measures

Primary outcome

The primary outcome will be extreme PTB < 28 weeks.

Secondary outcome

Secondary outcomes include a composite for adverse neonatal outcome, PTB < 24, 32 and 34 weeks,GA at delivery, PPROM, days on ventilation support, in NICU, maternal quality of life and maternal outcomes, and societal costs. Outcome measures are in line with the core outcome sets for evaluation of interventions to prevent PTB.

Study description

Background summary

Twin pregnancies have a high risk on extreme preterm birth (PTB) at less than 28 weeks of gestation which is associated with increased risk of neonatal morbidity and mortality. In the Netherlands, 250 women with a twin pregnancy deliver at < 28 weeks per year, resulting in 157 perinatal deaths and 343 surviving neonates of whom a large proportion, after a long hospital stay, suffer from the long term neurodevelopmental problems after extreme preterm birth. PTB is multifactorial in its origin and it is unlikely that one strategy will reduce all PTB. An asymptomatic short cervix (<= 25 mm) or detection of asymptomatic dilatation at midpregnancy in twin pregnancies is associated with high rates of extreme PTB and proven to be the best predictor for extreme PTB. Treatment strategies such as vaginal or intramuscular progesterone or pessary universally applied for all twin pregnancies have so far failed to be effective in reducing PTB rates. A possible effective surgical method to reduce extreme PTB in twin pregnancies with a short cervix or asymptomatic dilatation at midpregnancy is a minor operative procedure, the placement of a vaginal cerclage.

Hypothesis : A vaginal cerclage in women with a twin pregnancy and a midpregnancy short cervix will reduce extreme PTB and perinatal mortality compared to standard treatment

Study objective

To assess the effectiveness of a cerclage in women with a twin pregnancy with a midpregnancy short cervix compared to standard treatment (no cerclage) in the prevention of extreme preterm birth (PTB) < 28 weeks of GA.

Study design

International multicenter randomized controlled trial, with economic analyses alongside it.

Intervention

Vaginal cerclage

Study burden and risks

Burden:All participating women will be enrolled after a transvaginal cervical length measurement. Women will be counseld at the participating hospital. The participating hospital can decide to measure the cervical length again and if indicated perform physical examination to detect possible cervical dilatation. Eligible women will be randomly allocated to receive either a cervical cerclage or not. A cervical cerclage will be placed before 24weeks of gestation, and will stay in situ up to 36 weeks gestation or until delivery, whatever comes first. The procedure involves occlusion of the cervix by means of a cervical suture or stitch, which is performed in the operation theatre under general or spinal anesthesia and this is an invasive procedure.

Risk: A vaginal cerclage is a minor and safe surgical procedure commonly performed in singleton pregnancies with a short cervix or dilatation and a previous preterm birth in all the participating centers, thus there is experience in the participating hospitals. Potential complications of a cerclage are infection, premature rupture of membranes , cervical laceration or bleeding and anesthesia-related complications, occurring in approximately 0.3-2.5 %.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Women above the age of 16 years with a twin pregnancy and an asymptomatic short cervix or dilatation at routine ultrasound investigation below 24 weeks of pregnancy

Exclusion criteria

- Women with a mono-amniotic twin pregnancy
- Women with twin pregnancy in which one or both children are diagnosed with a major structural, congenital or chromosomal abnormality that is likely to influence the composite adverse neonatal outcome.
- Women with dilatation of the cervix and signs of clinical intra-uterine infection, defined by the presence of fever >= 38 degrees Celsius.
- Women with overt symptoms of preterm labour at time of measurement of short cervix (regular contractions, PPROM, recurrent blood loss).
- Women with a placenta previa, defined as a placenta position covering the

internal ostium of the cervix.
- Women who do not master the Dutch of English language and therefore not able to give written consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2023
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	17-03-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82609.018.22