Does Sildenafil improve the neonatal prognosis in severe early onset growth restriction?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28320

Source
Nationaal Trial Register

Brief title
The Dutch STRIDER

Health condition

Fetal growth restriction

Sponsors and support

Primary sponsor: Academisch Medisch Centrum, Amsterdam
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Intact neonatal survival until term age

Secondary outcome

1) To evaluate whether Sildenafil citrate, compared to placebo, increases the likelihood of improved fetal growth velocity assessed by ultrasound abdominal circumference measurements (AC);

2) To evaluate whether Sildenafil citrate, compared to placebo, increases the likelihood of age-adequate performance on the two-year Bayley scales of infant development (BSID)-III (composite cognitive score and composite motor score);

3) To assess co-incidence and severity of the maternal syndrome of pre-eclampsia / HELLP-syndrome

Study description

Background summary

Rationale: Severe, early-onset fetal growth restriction (FGR) due to placental insufficiency is associated with a high risk of perinatal morbidity with long-lasting sequelae and mortality. Placental insufficiency is the result of abnormal formation and function of the placenta (placentation) with inadequate remodelling of the maternal spiral (uteroplacental) arteries. There is currently no therapy available with demonstrated effectiveness. Evidence suggests Sildenafil citrate improves uteroplacental blood flow, growth, and meaningful outcomes.

Objective: To evaluate the effectiveness of sildenafil (versus placebo) in achieving healthy perinatal survival.

Study design: Multicenter nationwide randomized placebo-controlled clinical trial.

Study population: Women with a singleton pregnancy between 20 and 30 weeks with severe fetal growth restriction of likely placental origin, and with estimated significant likelihood of perinatal death.

Intervention: Sildenafil 25mg or placebo tablet orally three times daily.

Main study parameters/endpoints: Perinatal healthy survival, i.e. survival without severe neonatal morbidity at term age.

Study objective

Sildenafil citrate increases the likelihood of intact neonatal survival until term age for fetuses of pregnancies complicated by severe early-onset fetal growth restriction.

Study design

Term age, at discharge, at two years age (Bayley scales of infant development (BSID)-III)

Intervention

Sildenafil 25 mg or look-alike placebo tablets three times daily orally from randomization until delivery

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria ((I OR II) AND III):

I. At 20+0-27+6 weeks: an ultrasound measurement of the fetal abdominal circumference (AC) <3rd percentile for gestational age or an ultrasound estimate of fetal weight (EFW) <5th percentile

OR

II. At 28+0-29+6 weeks: an ultrasound estimate of fetal weight (EFW) <700 grams using Hadlock C formula

AND

III. Likely placental origin defined by (a AND/OR b AND/OR c AND/OR d)

a. The presence of uterine artery notching

b. Abnormal flow velocity patterns of the umbilical artery or middle cerebral artery

c. Maternal hypertensive disorders

d. Low PlGF in point-of-care assessment

Exclusion criteria

I. Plan to terminate pregnancy for maternal or fetal indication within days

II. Known multiple pregnancy

III. Identified congenital anomalies or congenital infection

IV. Maternal age at eligibility <18 years

V. Cocaine use

VI. Current use of sildenafil

VII. Current use of cyp3A5 inhibitors: amiodaron, azitromycine, ciclosporine, claritromycine, diltiazem, erytromycine, fluconazol, itraconazol, ketoconazol, verapamil, voriconazol.

VIII. Recent myocardial infarction or stroke

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	354
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-08-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47435
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4592
NTR-old	NTR4751
CCMO	NL41894.018.12
OMON	NL-OMON47435

Study results