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

Gepubliceerd: 13-08-2014 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28320

Bron
Nationaal Trial Register

Verkorte titel
The Dutch STRIDER

Aandoening

Fetal growth restriction

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum, Amsterdam
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Intact neonatal survival until term age

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	354
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47435
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten