The Dutch STRIDER (Sildenafil TheRapy In Dismal prognosis Early-onset intrauterine growth Restriction) Trial

Published: 05-06-2014
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We aim to compare the effectiveness of sildenafil versus placebo in achieving healthy perinatal survival, in women with singleton pregnancies with severe fetal growth restriction of placental origin.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Foetal complications
Study type	Interventional

Summary

ID

NL-OMON47435

Source
ToetsingOnline

Brief title
Dutch STRIDER

Condition

- Foetal complications

Synonym
Fetal growth restriction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: fetal growth restriction, placental insufficiency, sildenafil

Outcome measures

Primary outcome

Perinatal healthy survival, i.e. survival without severe neonatal morbidity at

term age.

Secondary outcome

Long-term healthy survival; fetal growth during further pregnancy; incidence of

maternal hypertensive disorders;

Study description

Background summary

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 proven therapy available. There is in vitro and in vivo evidence to suggest that Sildenafil citrate may offer a potential therapeutic strategy to improve uteroplacental blood flow in FGR pregnancies, and thus growth.

Study objective

We aim to compare the effectiveness of sildenafil versus placebo in achieving healthy perinatal survival, in women with singleton pregnancies with severe fetal growth restriction of placental origin.

Study design

Multicenter randomized double blind placebo-controlled clinical trial.

Intervention

Sildenafil 25mg or placebo tablet orally 3 times daily until fetal death, delivery or 32 weeks of gestation (whichever comes first).

Study burden and risks

Today there is no therapy for severe placental insufficiency at these gestational ages, current management is wait and see. There is a theoretical small risk of fetotoxicity, but in light of the background risk of the condition and the potential benefits these are probably negligible. Patients in this study don't have to pay extra visits to the hospital; they will undergo routine care. There will be one extra blood sample taken. There are no questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria ((I OR II) AND III):
I. at 200-276 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 280-296 weeks: an ultrasound estimate of fetal weight (EFW) <700 grams
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

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

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	19-01-2015
Enrollment:	354
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Viagra
Generic name:	sildenafil
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	22-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2016
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2018
Application type:	Amendment
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

ID: 28320
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-004112-63-NL
CCMO	NL41894.018.12
OMON	NL-OMON28320