Low dose aspirin in the Prevention of Recurrent Spontaneous Preterm Labour

Published: 22-02-2016
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To assess the effectiveness of low dose aspirin compared with placebo in prevention of recurrent spontaneous preterm birth.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON47921

Source
ToetsingOnline

Brief title
APRIL-study

Condition

- Neonatal and perinatal conditions

Synonym
prematurity, preterm birth, preterm labour

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: aspirin, preterm birth, prevention, recurrent

Outcome measures

Primary outcome

The primary outcome measure will be premature delivery, defined as a GA < 37 weeks.

Secondary outcome

Secondary outcomes will be a composite poor neonatal outcome (including BPD, PVL > grade 1, IVH > grade 2, NEC, ROP, culture proven sepsis and perinatal death, number of days on ventilation support, days of admission on the NICU, convulsions, asphyxia, proven meningitis, pneumothorax and total days in hospital until 3 months corrected age. Furthermore preterm delivery < 28 weeks, < 32 weeks, < 34 weeks of GA will be calculated, as well as IUGR defined as birth weight < p10. Preterm delivery will be analysed as spontaneous, induced or as a combination. Maternal outcomes include maternal side effects maternal mortality, maternal morbidity and major ante- or post-partum haemorrhage.

Study description

Background summary

Recurrent spontaneous preterm birth is a major problem in obstetrics and affects around 2500 pregnancies annually in the Netherlands. It has a great impact on both patients and national healthcare.

Study objective

To assess the effectiveness of low dose aspirin compared with placebo in prevention of recurrent spontaneous preterm birth.

Study design

Multicenter, randomized, double blinded, placebo controlled trial. Local protocol for prevention of preterm labour can be followed alongside the study protocol.

Intervention

Low dose aspirin (80mg) versus placebo, initiated from 8-16 week up to 36 weeks of gestation.

Study burden and risks

This study will be the first to asses the effectiveness of aspirin on the prevention of recurrent spontaneous preterm birth. Extensive research has already been performed on the effectiveness of aspirin to prevent other pregnancy complications such as preeclampsia and intrauterine growth restriction. For the prevention of these pregnancy complications the effectiveness has been established. The potential benefit of low dose aspirin in this population will be prolongation of pregnancy duration and improvement of neonatal outcome.
The potential risks are confined to mild discomfort in the epigastric region. Aspirin is a safe intervention in pregnancy as a recent review commissioned by the 'U.S. Preventive Services Task Force' concluded.
The burden en risk of participation are considered minimal.

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

Women with a singleton pregnancy with a previous spontaneous preterm birth (in a singleton pregnancy), defined as birth at a gestational age between 22 and 37 weeks

Exclusion criteria

Women with a history of indicated preterm births for maternal reasons such as preeclampsia or HELLP and for fetal reasons such as intra uterine growth restriction.

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:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2016
Enrollment:	406
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Low dose aspirin
Generic name:	acetylsalicylic acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	20-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	04-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	26-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2018
Application type:	Amendment
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Approved WMO Date:	19-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2020
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015-003220-31-NL
CCMO	NL54463.018.15

Study results

Date completed:	27-03-2020
Actual enrolment:	406