Follow-up of the FRUIT-RCT; aspirin resistance and cardiovascular risk factors in women after recurrent hypertensive disorders in pregnancy

Published: 02-03-2015
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1a. Determine whether the effect of low-molecular-weight heparin can be explained by aspirin resistance. 1b. Assess the consistency of aspirin resistance during and after pregnancy measured with several complementary devices. 2. Determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON41727

Source
ToetsingOnline

Brief title
Follow-up FRUIT-RCT

Condition

- Maternal complications of pregnancy

Synonym
aspirin resistance and cardiovascular risk factors

Research involving
Human

Sponsors and support

Primary sponsor: Verloskunde en Gynaecologie

Source(s) of monetary or material Support: geld vanuit participatie aan IPDMA;AFFIRM studie

Intervention

Keyword: aspirin resistance, cardiovascular risk factors, hypertensive disorders of pregnancy, thrombophilia

Outcome measures

Primary outcome

Aspirin resistance and cardiovascular risk factors

Secondary outcome

Metabolic syndrome

Study description

Background summary

The multicenter FRUIT-RCT demonstrated that adding low-molecular-weight heparin (LMWH) to the standard care aspirin, is beneficial in preventing early-onset hypertensive disorders of pregnancy (HD) in women with inheritable thrombophilia. Bujold et al suggested in a letter to the editor, responding to the FRUIT-RCT1 that the effect of LMWH could have been mainly beneficial in the subgroup of women who are resistant to aspirin. To evaluate this potential relationship we perform a two stage experiment: firstly evaluation of aspirin resistance in the non-pregnant FRUIT-RCT, and secondly the evaluation of aspirin resistance during pregnancy and post-puerperium.
Furthermore, we want to assess the prevalence of cardiovascular risk factors in women with inheritable thrombophilia and a history of recurrent HD. We want to examine if women with a history of recurrent hypertensive disorder of pregnancy develop cardiovascular risk factors more frequently than women with a history of single HD.

Study objective

1a. Determine whether the effect of low-molecular-weight heparin can be explained by aspirin resistance.
1b. Assess the consistency of aspirin resistance during and after pregnancy measured with several complementary devices.
2. Determine cardiovascular risk factors in the FRUIT-RCT; women with and

without recurrent HD.

Study design

To answer question 1a and 2, we will perform a follow-up study of the FRUIT-RCT1 cohort. To answer question 1b (which we need for question 1a), we will perform a longitudinal cohort study in women who have an indication for aspirin usage during pregnancy to reduce the change for (recurrent) HD.

Intervention

not applicable

Study burden and risks

Women will be visited 3 times in their regional hospital, of in VUmc. We'll ask them to fill in a questionnairre, perform physical examination and collect blood samples three times. These methods of research are safe and hardly invasive. The venous blood sampling can result in a hematoma, infection or vasovagal reaction.

Knowledge about aspirin resistance probably makes it possible in the future to individualize dose administration for patient with an indication for aspirin usage. If women have cardiovascular risk factors, they will be sent to their general practitioner for further treatment.
We will inform patients about the presence or absence of aspirin resistance, although it has no further implications in their pregnancy.
Few studies examined the potential influence of aspirin resistance and the effect on recurrent HD. This makes these studies of additional value to the current literature. Moreover, no prospective study has been performed to see whether recurrent HD is associated with a change in the incidence of cardiovascular risk factors compared to single HD.

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

For question 1a en 2: Inclusion in the FRUIT-RCT and living in the Netherlands. ;For question 1b: indication of aspirin use during pregnancy.

Exclusion criteria

- Diabetes Mellitus;
- Drugs that are known to alter platelet function (e.g. NSAID*s, tirofiban, eptifibatide, abciximab, clopidogrel, prasugel, ticagrelor, beta-lactam antibiotics, dextran, SSRI*s, clomipramine & amitriptyline, dipyridamole, verapamil, diltiazem , ginkgo biloba, ginseng, St John*s wort) within 2 weeks before testing.
- Major surgical procedure within one week before enrollment;
- Recent cardiovascular event < 3 months
- Alcohol use one day before testing aspirin resistance
- Abnormal cell count.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2015
Enrollment:	68
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aspirin
Generic name:	acetylsalicylacid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	02-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-03-2015
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

ID: 24125
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2014-004739-38-NL
CCMO	NL51093.029.14
OMON	NL-OMON24125

Study results

Date completed: 20-01-2017

Results posted: 29-01-2017

Actual enrolment: 52

First publication
20-06-2016