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

No registrations found.

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

Summary

ID

NL-OMON24125

Source
Nationaal Trial Register

Brief title
Follow-up FRUIT-RCT

Health condition

Hypertensive disorders of pregnancy
Preeclampsia
Thrombophilia
Aspirin resistance
Cardiovascular risk factors

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: None

Intervention

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

1: aspirin resistance is related to the occurrence of hypertensive disorders of pregnancy.

2: women with a history of recurrent hypertensive disorder of pregnancy develop cardiovascular risk factors more frequently than women with a history of single hypertensive disorder of pregnancy.

Study design

Start as soon as possible.

Intervention

Participants of the previous FRUIT-RCT receive 10 days aspirin.

For the parallel study women need to have an indication for aspirin usage in pregnancy.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion in the previous FRUIT-RCT and living in the Netherlands.

For the parallel study: 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
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2015
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-03-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41727
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4861
NTR-old	NTR5106
CCMO	NL51093.029.14
OMON	NL-OMON41727

Study results