

# Effects of naturopathic medicine on platelet function and coagulation measurements

<b>Submission date</b> 11/05/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/06/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many patients undergoing surgery use naturopathic drugs (a form of alternative medicine). Several of these have been reported to increase bleeding in patients. The Swedish Medical Products Agency recommends that patients stop taking the naturopathic medicines echinacea, fish oil, ginkgo biloba, ginseng, St. John's wort, valeriana and garlic two weeks before they have surgery. The primary aim of this pilot study is to examine the effects of these naturopathic drugs on the ability of the blood to clot using two different methods; the multiple electrode platelet aggregometer (Multiplate) and the viscoelastic rotational thromboelastometer (ROTEM). A secondary aim was to evaluate the effect of in vitro added ASA prior to Multiplate analyses in blood from healthy volunteers who had ingested Omega-3 in normal dose.

### Who can participate?

Adult healthy volunteers

### What does the study involve?

Participants all take a standard recommended dose of one of the neuropathic drugs to be tested for seven days. Blood samples are taken throughout the study period to assess platelet function and coagulation (both important for blood clotting),

### What are the possible benefits and risks of participating?

There are no benefits, except for free naturopathic drugs, of participating in this study. The naturopathic drugs in this study can be bought over the counter without prescription and our assessment is that the drugs studied are harmless.

### Where is the study run from?

Skåne University Hospital, Lund (Sweden)

### When is the study starting and how long is it expected to run for?

August 2014 to April 2015

### Who is funding the study?

Lund University

Who is the main contact?  
Dr Thomas Kander

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Thomas Kander

**Contact details**  
Skåne University Hospital  
Lund  
Sweden  
22185

## Additional identifiers

**Protocol serial number**  
1a

## Study information

**Scientific Title**  
Effects of naturopathic medicine on Multiplate and ROTEM: a prospective experimental pilot study on healthy volunteers

**Study objectives**  
Current study hypothesis as of 31/01/2020:  
The aim of this pilot study was to examine the effects of the 7 different naturopathic drugs listed by the Swedish Medical Products Agency, utilizing the multiple electrode platelet aggregometer (Multiplate) and the viscoelastic rotational thromboelastometer (ROTEM) in healthy humans after 7 consecutive days of peroral intake. A secondary aim was to evaluate the effect of in vitro added Aspirin (ASA) to blood samples prior to Multiplate analyses

Previous study hypothesis:  
The aim of this pilot study was to examine the effects of the 7 different naturopathic drugs listed by the Swedish Medical Products Agency, utilising the multiple electrode platelet aggregometer (Multiplate) and the viscoelastic rotational thromboelastometer (ROTEM) in healthy humans after 7 consecutive days of peroral intake.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Regional Ethical Review Board, Lund, Sweden, ref: 2010/482.

**Study design**

Single-centre experimental study

**Primary study design**

Interventional

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Study on healthy volunteers

**Interventions**

Thirty five healthy volunteers gave signed consent to ingest one of the listed naturopathic drugs for 7 days. Each naturopathic drug was taken in a recommended standard dose by 5 volunteers. ROTEM clot initiation (CT), clot formation (CFT),  $\alpha$ -angle (AA) and clot structure (MCF) were analysed with tissue factor activated (EXTEM) and native (NATEM) assays. The Multiplate platelet aggregation area under curve (AUC) was measured with adenosine diphosphate (ADP), collagen (COL) and arachidonic acid (ASPI) assays.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Not provided at time of registration

**Primary outcome(s)**

Platelet function measured with Multiplate

**Key secondary outcome(s)**

Coagulation evaluation measured with ROTEM

Primary and secondary outcomes were measured continuously during the recruitment, i.e. 1 November -- 30 November, 2014

**Completion date**

15/12/2019

**Eligibility**

**Key inclusion criteria**

Adult healthy volunteers

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Smoking
2. Intake of any kind of anticoagulant or antithrombotic medicine including recent intake of aspirin and non-steroid anti-inflammatory drugs
3. Pregnancy or planned surgery

**Date of first enrolment**

01/11/2014

**Date of final enrolment**

12/12/2019

**Locations****Countries of recruitment**

Sweden

**Study participating centre**

Skåne University hospital

Getingevägen

Lund

Sweden

22185

**Sponsor information****Organisation**

Skåne University Hospital

**ROR**

<https://ror.org/02z31g829>

**Funder(s)****Funder type**

Not defined

**Funder Name**

N/A

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	17/02/2016		Yes	No
<a href="#">Results article</a>		02/07/2020	14/06/2023	Yes	No