

Effects of naturopathic medicine on platelet function and coagulation measurements

Submission date 11/05/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2023	Condition category 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
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22185

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Asprin (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

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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), α -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 measure

Platelet function measured with Multiplate

Secondary outcome measures

Coagulation evaluation measured with ROTEM

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

Overall study start date

01/08/2014

Completion date

15/12/2019

Eligibility

Key inclusion criteria

Adult healthy volunteers

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

35

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

Sponsor details

Department of Intensive- and Peri-operative Care
Getingevägen
Lund
Sweden
22185

Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Not defined

Funder Name

N/A

Results and Publications

Publication and dissemination plan

We are planning to publish the results of this study in a scientific journal during 2015.

Intention to publish date

01/07/2020

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?
Results article	results	17/02/2016		Yes	No
Results article		02/07/2020	14/06/2023	Yes	No