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Effects of naturopathic medicine on platelet function and coagulation measurements

Submission date	Recruitment status	[_] Prospectively registered
11/05/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2023	Other	

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
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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
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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