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Effect of pomegranate extract on carotid atherosclerosis

Submission date	Recruitment status	[ ] Prospectively registered
26/05/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/07/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/07/2012	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
To find out if pomegranate extract is good for the arteries.

Who can participate?
Patients attending the Stroke Prevention & Atherosclerosis Research Centre, at Western University, Canada, who have had ultrasound scans of their carotid arteries and are known to have plaque (a build up of cholesterol and fats) in the arteries are eligible for the study.

What does the study involve?
Participants will have an ultrasound scan of the carotid arteries before and one year after being randomized to take a tablet of pomegranate extract, or an inactive placebo once daily for a year. The ultrasound scan measures the amount of plaque in the arteries, and to see how quickly it worsens or improves over a year on the two treatments.

What are the possible benefits and risks of participating?
The main benefit is that participants will help contribute to new knowledge of how to prevent heart attacks and strokes. It is possible that patients randomized to pomegranate extract might have less worsening of their arteries during the year of the study, but that is unknown thats why the study needs to be done.

Where is the study run from?
Stroke Prevention & Atherosclerosis Research Centre (SPARC), Western University, Ontario, Canada

When is study starting and how long is it expected to run for?
July 2012 to July 2014

Who is funding the study?
POM Wonderful

Who is the main contact?
Tisha Mabb
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Contact information

Type(s)
Scientific

Contact name
Dr J. David Spence

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
POMSPARC 1

Study information

Scientific Title
A randomized, double-blind study to evaluate the effect of pomegranate extract on carotid atherosclerosis in patients with carotid artery disease

Acronym
POMPlaque Study

Study objectives
Pomegranate extract will slow the progression of carotid atherosclerosis compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Human Research Ethics Board, Western University, Ontario, Canada

Study design
Double-blind randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Atherosclerosis, carotid artery disease

Interventions
Pomegranate extract, 1000mg or an inactive placebo once daily for a year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rate of progression/regression of 3-dimensional plaque volume

Secondary outcome measures
1. Rate of progression/regression of carotid intima-media thickness
2. Rate of progression/regression of 3D carotid vessel wall volume
3. Change in insulin resistance measured by the HOMA and QUICKI indexes

Overall study start date
02/07/2012

Completion date
30/07/2014

Eligibility

Key inclusion criteria

1. Adult subjects, 18 years old and above
2. Patients with carotid plaque, as measured by 3-D ultrasound, having a mean baseline plaque volume of 200 mm3 (minimum of 100 mm3 and maximum of 900 mm3)
3. Subjects must be willing to give written informed consent and able to adhere to dosing schedule, visit schedule and phone follow-up assessment.
4. Subjects clinical laboratory tests (CBC, blood chemistries and urinalysis) must be within normal limits or clinically acceptable to the investigator.
5. Subjects must be free of any clinically significant disease that would interfere with the study evaluations.
6. Female subjects of childbearing potential must be using a medically accepted method of birth control prior to the first clinic visit and agree to continue its use during the study, or have been surgically sterilized (e.g. hysterectomy or tubal ligation). Females of childbearing potential should be counseled in the appropriate use of birth control while in this study.
7. Females who are not currently sexually active must agree and consent to use one of the above-mentioned methods should they become sexually active while participating in the study.
8. Female subjects of childbearing potential must have a negative serum pregnancy test (beta-hCG) at the first clinic visit.
9. Patients on cardiovascular medications will be allowed to enter the study provided that they are on a stable medication regimen for at least 6 weeks prior study entry and patients agree to remain on the same regimen for the duration of the study. Medications permitted include: lipid lowering drugs, antihypertensive drugs, multiple vitamins, beta-blockers, calcium-channel blockers, ACE inhibitors, nitrates, α-adrenergic blockers, thiazide diuretics, antiplatelet agents, or anticoagulants (e.g. warfarin)
10. Patients on a stable diet for at least 4 weeks prior entry into the study and willing to maintain this diet for the duration of the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Female subjects who are pregnant, intend to become pregnant, or are nursing
2. Subjects, who are in a situation or have any condition that, in the opinion of the investigator, may interfere with optimal participation in the study
3. Individuals with a history of mental instability, drug or alcohol abuse or individuals who have been treated or are being treated for severe psychiatric illness that, in the opinion of the investigator, may interfere with optimal participation in the study
4. Excessive alcohol consumption (more than 2 glasses per day or 14 glasses per week) or history of alcohol or drug abuse within the past 2 years.
5. Disorders of the hematologic, digestive, or central nervous systems, including cerebrovascular

disease and degenerative disease, that would limit study evaluation or participation
6. Known impairment of renal function (eGFR <50), dysproteinemia, nephrotic syndrome, or other renal disease
7. Active or chronic hepatobiliary or hepatic disease.
8. Patients with AST or ALT >2 x upper limit of the laboratory reference range
9. Patients who are known to have tested positive for human immunodeficiency virus (HIV)
10. Patients who are currently enrolled in another clinical drug study
11. Patients who have used any investigational drug within 30 days of the first clinic visit
12. Congestive heart failure NYHA Class III or IV
13. Uncontrolled cardiac arrhythmias within 3 months of study entry
14. Myocardial infarction or coronary bypass surgery or angioplasty within 3 months of study entry
15. Unstable or severe peripheral artery disease within 3 months of study entry
16. Unstable angina pectoris within 3 months of study entry
17. Type I or Type II diabetes mellitus that is poorly controlled (HbA1c > 9.0%) or newly diagnosed (within 3 months) or a change in antidiabetic pharmacotherapy [i.e. changes in dosage (with the exception of ± 10 units of insulin) or addition of new medication] within 3 months of screening or patients experiencing recent history of repeated hypoglycemia or unstable glycemic control.
18. Uncontrolled endocrine or metabolic disease known to influence serum lipids or lipoproteins. Clinically euthyroid subjects on replacement doses of thyroid hormone are eligible for enrollment

Date of first enrolment
02/07/2012

Date of final enrolment
30/07/2014

Locations

Countries of recruitment
Canada

Study participating centre
Stroke Prevention & Atherosclerosis Research Centre
Ontario
Canada
N6G 2V2

Sponsor information

Organisation
POM Wonderful, LLC (USA)

Sponsor details

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
POM Wonderful (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration