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A clinical trial to study the effects of Ayurvedic formulation Suved and Reimmugen (whole cow colostrum) in patients with atherosclerosis

Submission date
28/09/2016

Recruitment status
No longer recruiting

Registration date
07/11/2016

Overall study status
Completed

Last Edited
27/07/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atherosclerosis is a condition where the arteries become clogged with fatty substances, increasing the risk of blood clots that can block the flow of blood to the heart or brain. This can lead to life-threatening problems such as heart attacks, strokes and deep vein thrombosis (DVT). Ayurveda is a traditional system of medicine that has been practiced in the Indian subcontinent for over 3000 years. It is based on the belief that health and wellness depend on a delicate balance between the mind, body, and spirit. The aim of this study is to assess the effects of the Ayurvedic formulation Suved and Reimmugen (cow colostrum, a form of milk) in patients with artherosclerosis.

Who can participate?
Patients aged 18 or over with artherosclerosis

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group take Suved and Reimmugen. Participants in the other group take a placebo (dummy drug). Participants take these medicines by mouth as capsules for a period of 3 months in addition to their ongoing medication to study the additional benefit to them. All participants undergo tests before treatment and after 3 months of treatment which include ultrasound scans of the heart, carotid artery and lower limbs, and blood tests. Participants' ongoing regular treatment is not changed.

What are the possible benefits and risks of participating?
Possible benefits include relief from symptoms associated with blood clots and cardiac (heart) weakness. The medicines have been used for over 7 years, no side effects have been recorded, and they can be taken with conventional medicines.

Where is the study run from?
Smt. Kashibai Navale Medical College (India)

When is the study starting and how long is it expected to run for?
September 2016 to September 2018

Who is funding the study?
Health Solutions (India)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02920125

Clinical Trials Registry - India (CTRI)
CTRI/2018/02/011848

Protocol serial number
SKNMC - HS/SHARP/2016

Study information

Scientific Title
A study to evaluate the results of integrative treatment (Ayurvedic capsules Suved and Reimmugen) for vascular disease

Acronym

SHARP

Study objectives
An equivalence trial in a pragmatic study of the clinical advantages and outcome on addition of Ayurvedic herbal formulation SUVED and cow colostrum Reimmugen to patients with vascular disease complications like ischemic heart disease (IHD), coronary artery disease (CAD), cardiovascular disease (CVD), deep vein thrombosis (DVT), and peripheral arterial disease (PAD). These advantages are clinical (intima-media thickness (IMT) studies) and functional in changes of symptoms associated with atherosclerosis/vascular blockages.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Smt. Kashibai Navale Medical College and General Hospital, 05/10/2016, ref: SKNMC/Ethical/App/2015/115

Primary study design
Interventional

Study design
Interventional double-blind placebo-controlled single-centre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vascular disease, atherosclerosis

Interventions
Patients are randomised to one of two groups:
1. Suved (Ayurvedic formulation, FDA India approved) and whole cow colostrum Reimmugen. Dosage decided by regular Ayurvedic use Suved 500mg one capsule twice daily: Reimmugen 300 mg one capsule three times daily in chronic subjects. Dose increased to Suved one capsule three times daily and Reimmugen two capsules three times daily in chronic acute subjects.
2. Placebo (everyday grain flour in same packaging to mask content)

These will be given for a period of 3 months in addition to ongoing medication to study the additional benefit to patients in their functional and clinical investigations.

Investigations done pre treatment and after 3 months treatment include the following: electrocardiogram (ECG), 2D echo cardiogram, carotid Doppler, and lower limb Doppler where necessary, angiography in few cases who opt to take the investigations, not compulsory, regular complete blood count (CBC), lipid profile, liver function test (LFT), renal function test (RFT).

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Suved, Reimmugen

Primary outcome(s)
Restoration of carotid IMT to a non-pathological state, supported with positive changes in functionality and relief from associated symptoms:
1. Clinical investigations will be compared pre - post treatment to evaluate percent changes in IMT and cardiac function as a mark of reversal of atherosclerosis and relief from symptoms associated with blockages in blood vessels due to atherosclerosis. IMT measurements are taken as standard to evaluate atherosclerosis and 2D echo taken for cardiac perfusion.
2. Functional changes considered on the basis of symptoms of chest pain, breathlessness, stamina of walking or performing daily chores.
Measured at baseline and at the end of 3 months of treatment.

Key secondary outcome(s)
Development of ischaemic events in other circulations (e.g., in a stroke patient, evaluation of coronaries), assessed at baseline and at the end of 3 months of treatment.

Completion date
01/09/2018

Eligibility

Key inclusion criteria
Males or females aged 18 or over with a diagnosis of vascular disease leading to IHD, CAD, CVD, DVT or PAD at any stage

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant and lactating women
2. Patients below age of 18
3. Acute IPD operative condition
4. Patients undergoing interventional procedures/surgical treatments other than for vascular disease, until they are discharged from intensive care
5. Haemorrhagic cerebrovascular stroke

Date of first enrolment
09/10/2016

Date of final enrolment
01/09/2018

Locations

Countries of recruitment
India

Study participating centre
Smt. Kashibai Navale Medical College
Navle
Pune
India
411041

Sponsor information

Organisation
Health Solutions

Organisation
Smt. Kashibai Navale Medical College

Funder(s)

Funder type
Industry

Funder Name
Health Solutions (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date