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Clinical acceptability study in patients suffering from chronic venous disease (CVD) comparing micronized purified flavonoid fraction (MPFF) 1000 mg, one tablet daily, to MPFF 500 mg tablet twice a day

Submission date 05/05/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/06/2014	**Overall study status** Completed	
Last Edited 18/04/2018	**Condition category** Circulatory System	

Plain English Summary
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-05682-107

Study information

Scientific Title
Clinical acceptability study of micronized purified flavonoid fraction 1000 mg, one tablet per day compared to micronized purified flavonoid fraction 500 mg, two tablets daily after 8 weeks of treatment in patients suffering from symptomatic chronic venous disease (CVD): an international, multicenter, double-blind, randomized, parallel group study

Study hypothesis
To demonstrate the clinical acceptability of Micronized Purified Flavonoid Fraction 1000 mg (one tablet per day) compared to Micronized Purified Flavonoid Fraction (Daflon®/Detralex®) 500 mg (two tablets per day) in patients suffering from CVD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
International multicenter double-blind randomized parallel-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Chronic venous insufficiency

Interventions
Participants will be randomized to be treated with either one tablet taken daily of Micronized Purified Flavonoid Fraction 1000 mg or two 500 mg tablets taken daily for 8 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Daflon/Detralex

Primary outcome measure
Safety (clinical acceptability) assessed at each visit (week 0, week 2, week 4 and week 8). Safety assessment takes into account adverse events, weight, sitting blood pressure and heart rate, laboratory examination and leg pain by Visual Analog Scale.

Secondary outcome measures
There are no secondary outcomes.

Overall study start date
19/12/2013

Overall study end date
01/07/2014

Eligibility

Participant inclusion criteria
1. Male or female patient aged 20 to 70 years old (inclusive)
2. Out-patient
3. Suffering from primary chronic venous disease (leg pain greater or equal to 4 cm on Visual Analog Scale)
4. Clinical class C0s to C4s on the most affected leg (CEAP classification)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
150

Participant exclusion criteria
1. Pregnancy, breastfeeding or possibility of becoming pregnant
2. Recent non-authorized nonpharmacological treatments (sclerotherapy; surgical treatment of varicose veins, angioplasty; endovascular devices)
3. Recent compression therapy and/or physical therapy of legs
4. Active venous thrombosis, significant chronic deep venous obstruction leading to venous

claudication and significant compression therapy
5. All causes of leg pain in lower limbs others than CVD symptoms

Recruitment start date
19/12/2013

Recruitment end date
01/07/2014

Locations

Countries of recruitment
Russian Federation

Serbia

Study participating centre
Russian State Medical University
Moscow
Russian Federation
117997

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
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92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Current version as of 28/03/2018:
Summary results are published in https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

IPD sharing plan: The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

Previous version as of 24/01/2018:
Publication plan:
All phases - Interventional studies ending before 01/10/2018: Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com/ if a Marketing Authorisation has been granted after 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No