

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/06/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/04/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

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

Contact information

Type(s)

Scientific

Contact name

Prof Alexander Kirienko

Contact details

Russian State Medical University
1, Ostrovityanova Street
Moscow
Russian Federation
117997

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clinicaltrials@servier.com

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 objectives

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

Health condition(s) or problem(s) studied

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/Detralext

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

Completion date

01/07/2014

Eligibility**Key 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

Key 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

Date of first enrolment

19/12/2013

Date of final enrolment

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

France

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