

# 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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>05/05/2014   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>06/06/2014 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>18/04/2018       | <b>Condition category</b><br>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

-

clinicaltrials@servier.com

## Additional identifiers

### Protocol serial number

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

## Primary study design

Interventional

## Study design

International multicenter double-blind randomized parallel-group study

## Study type(s)

Treatment

## 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/Detralex

## Primary outcome(s)

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.

## Key secondary outcome(s)

There are no secondary outcomes.

**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

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**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)

**ROR**  
<https://ror.org/034e7c066>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Institut de Recherches Internationales Servier (France)

## Results and Publications

### 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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a> |         |              |            | No             | No              |