

Effects of micronised purified flavonoic fraction on microcirculation in women suffering from chronic venous disease

Submission date 20/07/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/08/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/04/2018	Condition category Circulatory System	☐ 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

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Contact details

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Additional identifiers

Protocol serial number

CL2-05682-099

Study information

Scientific Title

Effects of micronised purified flavonoic fraction on microcirculation in women suffering from chronic venous disease

Study objectives

Clinical efficacy of micronised purified flavonoic fraction over four menstrual cycles.

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

Single-centre double-blind randomised placebo-controlled parallel-group study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic venous disease

Interventions

Micronised purified flavonoic fraction 500 mg over four menstrual cycles versus placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Daflon®

Primary outcome(s)

Effects on microcirculatory and biological parameters over four menstrual cycles

Key secondary outcome(s)

Safety

Completion date

30/04/2012

Eligibility

Key inclusion criteria

Current inclusion criteria as of 29/11/2012:

1. Female suffering from primary chronic venous disease
2. Aged 18 to 30 years old

Previous inclusion criteria until 29/11/2012:

1. Female suffering from primary chronic venous disease
2. Aged 18 to 50 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Patients with irregular menstrual cycles
2. Women of childbearing potential without effective contraception

Date of first enrolment

22/07/2009

Date of final enrolment

30/04/2012

Locations

Countries of recruitment

Brazil

Study participating centre

Instituto de Biologia Roberto Alcantara Gomes

Rio de Janeiro

Brazil

20550-013

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 1st January 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