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

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

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 Eliete Bouskela

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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

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 measure

Effects on microcirculatory and biological parameters over four menstrual cycles

Secondary outcome measures

Safety

Overall study start date

22/07/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

240

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)

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

Publication plan:

Summary results are published in https://clinicaltrials.servier.com.

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 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