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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2009	**Overall study status** Completed	
Last Edited 18/04/2018	**Condition category** 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

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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