ISRCTN28639953 https://doi.org/10.1186/ISRCTN28639953

Clinical acceptability study in patients suffering from acute hemorrhoidal disease comparing micronized purified flavonoid fraction (MPFF) 1000 mg tablet, to MPFF 500 mg tablet

Submission date 05/05/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/06/2014	**Overall study status** Completed	
Last Edited 18/04/2018	**Condition category** Circulatory System	

Plain English Summary
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
CL3-05682-108

Study information

Scientific Title
Clinical acceptability study of micronized purified flavonoid fraction 1000 mg tablets and micronized purified flavonoid fraction 500 mg tablets after 7 days of treatment followed by a follow-up period of 7 days in patients suffering from acute hemorroidal disease (HD)

Study hypothesis
To demonstrate the clinical acceptability of MPFF 1000 mg and MPFF 500 mg tablets in patients suffering from hemorrhoidal disease during a 7-day treatment period, followed by follow-up period of 7 days.

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

Condition
Hemorrhoidal disease

Interventions
All participants will receive 3 g/day of MPFF during 4 days and 2 g/day of MPFF during the 3 following days. Participants will be randomly allocated to receive this dose in the form of either 500 mg tablets or 1000 mg tablets. After the 7 days of treatment there will be a follow-up period of 7 days

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Safety (clinical acceptability) assessed at each visit (day 0, day 7, day 14). Safety assessment takes into account adverse events, weight, sitting blood pressure and heart rate, bleeding cessation evaluation by a 4-point scale, pain evaluation by Visual Analog Scale and laboratory examination

Secondary outcome measures
N/A

Overall study start date
16/12/2013

Overall study end date
13/06/2014

Eligibility

Participant inclusion criteria
1. Male or female patient aged 18 to 75 years old (inclusive)
2. Out-patient
3. Suffering from acute and non-complicated hemorrhoidal episode (acute pain with oedema assessed by a Visual Analog Scale and/or bleeding assessed by a 4-point scale)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
150

Participant exclusion criteria
1. Pregnancy, breastfeeding or possibility of becoming pregnant
2. Complicated hemorrhoidal disease (requiring surgery, stage IV prolapsed hemorrhoids, anal fissure, associated infection), patients presenting other anal bleeding pathologies
3. Laser therapy, anal surgery, canal radiation before inclusion

Recruitment start date
16/12/2013

Recruitment end date

13/06/2014

Locations

Countries of recruitment
Russian Federation

Serbia

Study participating centre
Federal State Institution 'State Scientific Center of Coloproctology' of Ministry of Health of Russian Federation
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
Results article	results	01/11/2016		Yes	No