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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 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

Protocol serial number
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 objectives
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)
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

Key secondary outcome(s))
N/A

Completion date

13/06/2014

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key 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

Date of first enrolment
16/12/2013

Date of final enrolment
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)

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?
Results article	results	01/11/2016		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes