

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/06/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/04/2018	Condition category Circulatory System	<input type="checkbox"/> 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

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 hemorrhoidal 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

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

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 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

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

Age group

Other

Sex

Both

Target number of participants

150

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)

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

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