A randomized, parallel-group, multicenter study to assess the efficacy and safety of vilaprisan in subjects with uterine fibroids

Published: 30-05-2017
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The primary objective of this study is to assess the efficacy and safety of vilaprisan in subjects with uterine fibroids compared to ulipristal. The secondary objective of this study is to evaluate the efficacy and safety of different treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON48550

Source
ToetsingOnline

Brief title
ASTEROID 5

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
leiomyoma, uterine fibroids

Research involving
Human

Sponsors and support

Primary sponsor: Bayer

Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: heavy menstrual bleeding, uterine fibroids

Outcome measures

Primary outcome

The primary objective of this study is to assess the efficacy of vilaprisan in

subjects with uterine fibroids compared to ulipristal acetate.

Secondary outcome

The secondary objective of this study is to evaluate the efficacy and safety of

different treatment regimens of vilaprisan in subjects with uterine fibroids.

Study description

Background summary

The PRM vilaprisan is being tested for the treatment of uterine fibroids. In two Phase 2 studies, vilaprisan has demonstrated a clinically meaningful reduction of symptoms associated with uterine fibroids, especially of heavy menstrual bleeding, improvements of patients* health-related quality of life and a reduction of fibroid size. Safety data from these studies showed a favorable safety profile. The active comparator in this study is approved in the participating countries for the treatment of moderate to severe symptoms of uterine fibroids.

Study objective

The primary objective of this study is to assess the efficacy and safety of vilaprisan in subjects with uterine fibroids compared to ulipristal.
The secondary objective of this study is to evaluate the efficacy and safety of different treatment regimens of vilaprisan in subjects with uterine fibroids.

Study design

Randomized, parallel-group, multi-center design. Screening period of up to 90 days.

Planned to be randomized: 1000 subjects as follows
* Treatment Group A1: 500 subjects
* Treatment Group A2: 500 subjects

Approximately 75% of eligible subjects will be randomized to one of two vilaprisan treatment groups (Groups A1 or A2) for about one year of treatment (subgroup 1).
The remaining eligible subjects (about 25%) will be randomized to one of two vilaprisan treatment groups (Groups A1 or A2) for about 2 years of treatment (subgroup 2).

In addition 199 subjects have been randomized to Treatment Group A3 or B prior to implementation of Protocol version 5.0. They will be given the option to continue in these Treatment Groups with vilaprisan 3/2 being assigned as medication to both Treatment Groups after implementation of protocol version 5.0. No new subjects will be randomized in Treatment Group A3 or B after implementation of Protocol version 5.0

Subgroup 1:
o Treatment Group A1: Vilaprisan, 4 treatment periods of 12 weeks, each separated by 1 bleeding episode (3/1 regimen)
o Treatment Group A2: Vilaprisan, 2 treatment periods of 24 weeks, separated by 2 bleeding episodes (6/2 regimen)
o Treatment Group A3/B: Vilaprisan, 3 treatment periods of 12 weeks, each separated by 2 bleeding episodes (3/2 regimen)

Subgroup 2:
o Treatment Group A1: Vilaprisan, 8 treatment periods of 12 weeks, each separated by 1 bleeding episode (3/1 regimen)
o Treatment Group A2: Vilaprisan, 4 treatment periods of 24 weeks, separated by 2 bleeding episodes (6/2 regimen)

Intervention

Subgroup 1:
o Treatment Group A1: Vilaprisan, 4 treatment periods of 12 weeks, each separated by 1 bleeding episode (3/1 regimen)
o Treatment Group A2: Vilaprisan, 2 treatment periods of 24 weeks, separated by 2 bleeding episodes (6/2 regimen)
o Treatment Group A3/B: Vilaprisan, 3 treatment periods of 12 weeks, each separated by 2 bleeding episodes (3/2 regimen)

Subgroup 2:
o Treatment Group A1: Vilaprisan, 8 treatment periods of 12 weeks, each separated by 1 bleeding episode (3/1 regimen)
o Treatment Group A2: Vilaprisan, 4 treatment periods of 24 weeks, separated by

2 bleeding episodes (6/2 regimen)

Study burden and risks

The drug applied in this study has been shown to have a favorable safety profile. Patients in this study are asked to fill out a daily diary on an electronic handheld device, including information about sanitary pads or tampons used on days with menstrual bleeding. Regular visits are scheduled once every three months of treatment, but due to the intermittent treatment breaks the actual average time window between visits is longer than three months. Besides these regular visits, extra visits are scheduled to monitor liver function. Patients will have to undergo endometrial biopsies with a pipelle de Cornier at pre-defined scheduled or unscheduled timepoints (up to 4 scheduled biopsies). 18-21 blood samples are planned in this study and three MRI examinations. the risk associated with these procedures is low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Women, 18 years or older at the time of Visit 1
2. Diagnosis of uterine fibroid(s) documented by ultrasound at screening with at least 1 fibroid with largest diameter more than 30 mm and less than 120 mm
3. Heavy menstrual bleeding (HMB) >80.0 mL documented by menstrual pictogram (MP) in a bleeding episode period during the screening period
4.Use of an acceptable non-hormonal method of contraception
5. An endometrial biopsy performed during the screening period, without significant histological disorder such as endometrial hyperplasia (including simple hyperplasia) or other significant endometrial pathology.

Exclusion criteria

1. Pregnancy or lactation (less than 3 months since delivery, abortion, or lactation before start of treatment)
2. Hypersensitivity to any ingredient of the study drugs
3. Hemoglobin values *6 g/dL or any condition requiring immediate blood transfusion (subjects with hemoglobin values *10.9 g/dL will be recommended to use iron supplementation).
4. Any diseases, conditions, or medications that can compromise the function of the body systems and could result in altered absorption, excessive accumulation, impaired metabolism, or altered excretion of the study drug including
5. Abuse of alcohol, drugs, or medicines (eg, laxatives)
6. Undiagnosed abnormal genital bleeding
7. Any diseases or conditions that might interfere with the conduct of the study or the interpretation of the results.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2018
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BAY1002670
Generic name:	vilaprisan

Ethics review

Approved WMO Date:	30-05-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-09-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-11-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-01-2018
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-04-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-04-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-06-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-06-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	24-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-12-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	10-01-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-01-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-02-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2016-002855-48-NL
CCMO	NL61736.100.17