Clinical trial results:
Uterine fibroids: Impact of ulipristal acetate 10 mg on ART results.

Summary

EudraCT number	2014-000964-16
Trial protocol	ES
Global end of trial date	31 May 2016

Results information

Result version number	v1 (current)
This version publication date	30 October 2020
First version publication date	30 October 2020

Trial information

Trial identification

Sponsor protocol code	1311-BCN-138-DG

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	IVI Valencia
Sponsor organisation address	Plaza Policia Local, Valencia, Spain,
Public contact	Daniela Galliano, IVI Valencia, +34 963050900, Daniela.Galliano@ivi.es
Scientific contact	Daniela Galliano, IVI Valencia, +34 963050900, Daniela.Galliano@ivi.es

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 May 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 May 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Demonstrate an 15% increase in the rate of clinical pregnancy in women with inoperable intramural fibroids not distorting the uterine cavity within a program OVD, after administration of uPA in a dose of 10 mg orally daily for 12 weeks

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 March 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 2
Worldwide total number of subjects	2
EEA total number of subjects	2

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients> 18 and <50 years Patients who undergo a first / second cycle OVD Patients who present within 1-3 intramural myomas> 2 cm and <5 cm that do not distort the cavity, Type 3 and 4 of the FIGO classification (Figure 1). Miomas inoperable for medical judgment or patient desire, you want to avoid the post-surgical time waiting 6 months / 1 year

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Arm title	ESMYA
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Acetate ulipristal
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pastille
Routes of administration	Oral use

Dosage and administration details:

10 mg/day

Number of subjects in period 1	ESMYA
Started	2
Completed	2

Baseline characteristics

End points

End points reporting groups

Reporting group title	ESMYA

Reporting group description: -

Primary: clinical pregnancy rate

End point title	clinical pregnancy rate[1]

End point description:

End point type	Primary

End point timeframe:

1 year

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Premature cancellation. Results have not been analysed

End point values	ESMYA			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: %				

Notes:

[2] - Premature cancellation. Results have not been analysed

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 3 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Premature cancellation. Results have not been analysed

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
31 May 2016	Lack of availibility of eligible subjects	-

Notes:

Limitations and caveats

None reported