Clinical trial results:
VAGINAL PRASTERONE in the treatment of VAGINAL ATROPHY IN PATIENTS WITH BREAST CANCER TREATMENT WITH AROMATASE INHIBITORS (VIBRA STUDY)

Summary

EudraCT number	2020-001077-79
Trial protocol	ES
Global end of trial date	30 December 2021

Results information

Result version number	v1 (current)
This version publication date	28 May 2026
First version publication date	28 May 2026

Trial information

Trial identification

Sponsor protocol code	HCB/2020/0212

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04705883
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fundació Clínic Recerca Biomèdica
Sponsor organisation address	C/ Villarroel 170, Barcelona, Spain,
Public contact	Secretaria de Ginecologia Clínic, Fundació Clínic Recerca Biomèdica, 34 392275436, secgine@clinic.cat
Scientific contact	Secretaria de Ginecologia Clínic, Fundació Clínic Recerca Biomèdica, 34 392275436, secgine@clinic.cat

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	01 December 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 November 2021
Global end of trial reached?	Yes
Global end of trial date	30 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Verify a clinical improvement of AVV without increasing levels of ultrasensitive blood estradiol in breast cancer survivors treated with
aromatase inhibitors by administering vaginal prasterone.

Protection of trial subjects:

The protection of trial subjects was ensured through several measures. The study was conducted in accordance with the principles of the Declaration of Helsinki and complied with applicable data protection regulations. The protocol was reviewed and approved by the Ethics Committee of Hospital Clínic of Barcelona (approval code: HCB/2020/021).
All participants provided written informed consent prior to inclusion. Only breast cancer survivors fulfilling strict inclusion and exclusion criteria were enrolled. Safety was closely monitored throughout the study period, including serial clinical evaluations and repeated measurements of ultrasensitive serum estradiol levels at each followup visit. Adverse events were actively recorded during all visits.
Given the lowrisk nature of the intervention, the pilot design, and the small sample size, no Independent Data Monitoring Committee was established.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2020
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: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	10
Number of subjects completed	10

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable. Open-label, single-arm pilot study.

Arms

Arm title	Prasterone

Arm description:

Single-arm treatment with vaginal prasterone (DHEA)

Arm type	Experimental
Investigational medicinal product name	Prasterone
Investigational medicinal product code	
Other name	DHEA, Intrarosa
Pharmaceutical forms	Vaginal capsule, soft
Routes of administration	Vaginal use

Dosage and administration details:

Prasterone 6.5 mg administered vaginally as a vaginal ovule. One ovule was used daily during the first month, followed by one ovule every other day for the remaining five months of treatment.

Number of subjects in period 1	Prasterone
Started	10
Completed	7
Not completed	3
Consent withdrawn by subject	1
COVID19 pandemic limitaons	2

Baseline characteristics

Reporting groups	
Reporting group title	Prasterone
Reporting group description:	
Single-arm treatment with vaginal prasterone (DHEA)	

Reporting group values	Prasterone	Total	
Number of subjects	10	10	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	56.8		
standard deviation	± 6.8	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	0	0	

End points

End points reporting groups

Reporting group title	Prasterone
Reporting group description:	
Single-arm treatment with vaginal prasterone (DHEA)	

Primary: Serum estradiol levels

End point title	Serum estradiol levels[1]
End point description:	
Change in ultrasensitive serum estradiol levels from baseline to 6 months of treatment with vaginal prasterone in breast cancer survivors treated with aromatase inhibitors.	
End point type	Primary
End point timeframe:	
Baseline to Month 6	

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: Serum estradiol levels at baseline and month 6 were analysed using a paired Wilcoxon signed-rank test. No statistically significant change was observed (two-sided p=0.9136)

End point values	Prasterone			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: pg/mL				
arithmetic mean (standard deviation)	4.3 (± 7.5)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From first administration of prasterone until end of 6-month follow-up.

Adverse event reporting additional description:

No treatment-related local adverse events were reported during the study. Three participants discontinued the study: one due to safety concerns despite partial symptom improvement, and two due to COVID-19-related follow-up limitations.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Prasterone

Reporting group description:

Single-arm treatment with vaginal prasterone (DHEA)

Serious adverse events	Prasterone		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Prasterone		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		

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: No non-serious adverse events related to prasterone were observed or recorded during the study follow-up period. Therefore, no non-serious adverse events are reported

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? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This was a small open-label pilot study including only 10 participants, with 7 completing the 6-month follow-up. The study lacked a control group and had limited statistical power. Hormone measurements were performed using immunoassay techniques that

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/35343852