

**Clinical trial results:****Randomized Clinical Trial comparing the endometrial transformation with 25 mg/day of subcutaneous progesterone (Prolutex) versus 50 mg/day intramuscular progesterone (Prontogest)****Summary**

EudraCT number	2015-000290-12
Trial protocol	ES
Global end of trial date	29 January 2016

Results information

Result version number	v1 (current)
This version publication date	31 October 2020
First version publication date	31 October 2020
Summary attachment (see zip file)	1412-BCN-087-AB Results (1412-BCN-087-AB Results.pdf)

Trial information**Trial identification**

Sponsor protocol code	1412-BCN-087-AB
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02567552
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	IVI Barcelona
Sponsor organisation address	Ronda del General Mitre, 14, 08017 Barcelona, Barcelona, Spain,
Public contact	Medicina Reproductiva, Clínica IVI Barcelona, 0034 932 063 000, agustin.ballesteros@ivi.es
Scientific contact	Medicina Reproductiva, Clínica IVI Barcelona, 0034 932 063 000, agustin.ballesteros@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	14 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 January 2016
Global end of trial reached?	Yes
Global end of trial date	29 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the predecidualización endometrial (ie, measuring the effects of progesterone in the endometrial glands and stroma in the luteal phase) and endometrial receptivity on Day 5 as gene expression, following daily administration of 25 mg / day of subcutaneous progesterone and 50 mg / day intramuscular progesterone, both for 5 days, to see if there are differences in the use of both progesterone.

Protection of trial subjects:

Monitoring and Insurance

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 April 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: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

1 year

Pre-assignment

Screening details:

Female aged between 18 and 34 years

- BMI between 18 and 28 kg/m²
- Endometrial thickness > 7 mm the day of progesterone treatment initiation (day of follicular puncture)
- Follicular maturation with a single bolus of GnRH agonist
- Egg donors who undergo a cycle of ovarian stimulation in the IVI Barcelona Centre
- Egg donors selected in accor

Period 1

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

Blinding implementation details:

Masked samples for histological evaluation and assessment of gene expression

Arms

Are arms mutually exclusive?	Yes
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Arm title	Prolutex
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Prolutex
Investigational medicinal product code	
Other name	Subcutaneous progesterona
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

25 mg/day

Arm title	Prontogest
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Prontogest
Investigational medicinal product code	
Other name	Intramuscular Progesterone
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

50 mg/day

Number of subjects in period 1	Prolutex	Prontogest
Started	12	12
Completed	12	11
Not completed	0	1
Adverse event, non-fatal	-	1

Baseline characteristics

Reporting groups

Reporting group title	overall trial
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Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	24	24	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	24	24	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	24	24	
Male	0	0	

End points

End points reporting groups

Reporting group title	Prolutex
Reporting group description:	-
Reporting group title	Prontogest
Reporting group description:	-

Primary: Predecidual Transformation

End point title	Predecidual Transformation
End point description:	Histologic dating of the endometrium at day 5: early secretory phase, media secretory phase or late secretory phase
End point type	Primary
End point timeframe:	5 days

End point values	Prolutex	Prontogest		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: %				
early secretory phase	1	2		
media secretory phase	7	8		
late secretory phase	4	1		

Statistical analyses

Statistical analysis title	Statistical Analysis for Predecidual Transformat
Comparison groups	Prolutex v Prontogest
Number of subjects included in analysis	23
Analysis specification	Post-hoc
Analysis type	other ^[1]
P-value	= 0.3395
Method	Chi-squared

Notes:

[1] - Pilot study

Adverse events

Adverse events information

Timeframe for reporting adverse events:

1 year

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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Reporting groups

Reporting group title	Prolutex
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Reporting group description: -

Reporting group title	Prontogest
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Reporting group description: -

Serious adverse events	Prolutex	Prontogest	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Prolutex	Prontogest	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 12 (41.67%)	4 / 12 (33.33%)	
General disorders and administration site conditions			
Discomfort in injection site			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pain in injection site			
subjects affected / exposed	0 / 12 (0.00%)	4 / 12 (33.33%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Breast inflammation			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

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

None reported