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ClinicalTrials.gov ID: NCT02567552

Study Identification

Unique Protocol ID:	1412-BCN-087-AB
Brief Title:	Clinical Trial Comparing Endometrial Transformation With Subcutaneous Progesterone Versus Intramuscular Progesterone
Official Title:	Randomized Clinical Trial Comparing Endometrial Transformation With Subcutaneous Progesterone (Prolutex) 25 mg/Day Versus Intramuscular Progesterone (Prontogest) 50 mg/Day
Secondary IDs:	2015-000290-12 [EudraCT Number]

Study Status

Record Verification:	February 2019
Overall Status:	Completed
Study Start:	May 2015 []
Primary Completion:	December 2015 [Actual]
Study Completion:	January 2016 [Actual]

Sponsor/Collaborators

Sponsor:	IVI Barcelona
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 11/06/2015 Board Name: Comité Ético de Investigación Hospital Clínic de Barcelona Board Affiliation: Hospital Clínic Phone: 932275786 Email: bgomez@clinic.ub.es; abernal@clinic.ub.es Address: C/ Villarroel 170 , 08036 Barcelona
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	No

Study Description

Brief Summary:	Study the endometrial predecidualization by using subcutaneous progesterone 25 mg/day versus intramuscular progesterone 50 mg/day, to determine whether there are differences in the endometrial transformation and endometrial receptivity.
Detailed Description:	The aim of this study is to compare predecidualization and endometrial receptivity as gene expression by using subcutaneous progesterone 25 mg/day versus intramuscular progesterone 50 mg/day in healthy women of childbearing age. Both, the two drugs and the doses administered in this clinical trial, are routine clinical practice. A controlled ovarian stimulation will be previously performed and following routine clinical practice for 10-12 days at standard doses of subcutaneous FSH 150-225 IU/day, according to BMI and number of antral follicles. A GnRH antagonist shall be administered, being initiated according to donor's follicular growth from greater or equal14 mm diameter follicles. Final maturation shall be performed with a bolus of GnRH agonist when there exist at least 3 follicles greater or equal17 mm diameter, and therefore performing follicular puncture 36 hours after the bolus of agonist has been administered. If the donor meets the inclusion criteria, she will be informed of the study and, if she agrees, she will sign the informed consent. Randomization shall be performed in 2 arms; arm 1 will be administered subcutaneous progesterone 25 mg/day (Prolutex; Angelini, Spain), and arm 2, intramuscular progesterone 50 mg/day (Prontogest IBSA, Italy). In each arm 12 donors (ITT population) will be included. The randomization to a treatment group shall be performed the day the follicular puncture has been programmed. To that purpose, a randomized consecutive sampling will be used by means of assignment tables. The medication will be administered by a person not involved in the assessments and responsible for group assignment, data centralization and drug assignment. At day 5 (5 days after follicular puncture):endometrial thickness measurement by means of transvaginal ultrasound and perform endometrial biopsy and take two samples: 1 sample to Anatomical Pathology and 1 sample to Endometrial Receptivity Array (ERA).

Conditions

Conditions:	Reproductive Techniques, Assisted
Keywords:	endometrial receptivity endometrial predecidualization endometrial genomics endometrial receptivity array

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Interventional Study Model:	Parallel Assignment Parallel Assignment
Number of Arms:	2
Masking:	Single (Outcomes Assessor) Masked samples for histological evaluation and assessment of gene expression
Allocation:	Randomized
Enrollment:	24 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Prolutex Subcutaneous progesterone	Drug: Subcutaneous progesterone subcutaneous progesterone 25 mg/day Other Names: • Prolutex
Active Comparator: Prontogest Intramuscular progesterone	Drug: Intramuscular progesterone intramuscular progesterone 50 mg/day Other Names: • Prontogest

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 34 Years

Sex: Female

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- 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 accordance with the requirements of Law 14/2006 of 26 May 2006 on Assisted Human Reproduction Techniques
- Informed consent has been signed and dated

Exclusion Criteria:

- Known allergy to progesterone formulations or their excipients
- Known allergy to estrogens
- Known thrombophilias
- Alcohol, drug or psychotropic medication dependence
- Concurrent participation in another study
- Concomitant medication that may interfere with the study medication and ovarian stimulation
- Failure to comply with the requirements for egg donors in accordance with Law 14/2006 of 26 May 2006 on Assisted Human Reproduction Techniques

Contacts/Locations

Central Contact Person: Evelin L Molina
Telephone: 935 316 301
Email: evelin.lara@ivi.es

Central Contact Backup:

Study Officials: Agustín B Boluda
Study Principal Investigator
IVI Barcelona

Locations: **Spain**
IVI Barcelona

Barcelona, Spain, 08017
Contact: Evelin L Molina 935 316 301 evelin.lara@ivi.es
Principal Investigator: Agustín B Boluda
Sub-Investigator: Evelin L Molina
Sub-Investigator: Ana Belén C Balazote
Sub-Investigator: Verónica G Martínez

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Overall Study

	Prolutex	Prontogest
Started	12	12
Completed	12	11 [1]
Not Completed	0	1

	Prolutex	Prontogest
Adverse Event	0	1

[1] dropout by pain in the puncture site

Baseline Characteristics

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Baseline Measures

		Prolutex	Prontogest	Total
Overall Number of Participants		12	12	24
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	12 participants	12 participants	24 participants
		26.92 (5.32)	25.58 (2.39)	26.25 (4.09)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	12 participants	12 participants	24 participants
	Female	12 100%	12 100%	24 100%
	Male	0 0%	0 0%	0 0%
Body Mass Index Mean (Standard Deviation) Unit of measure: kg/m^2	Number Analyzed	12 participants	12 participants	24 participants
		21.76 (2.88)	23.12 (2.79)	22.44 (2.86)

		Prolutex	Prontogest	Total
Height Mean (Standard Deviation) Unit of measure: cm	Number Analyzed	12 participants	12 participants	24 participants
		166.75 (5.10)	162.08 (3.50)	164.42 (4.90)
Weight Mean (Standard Deviation) Unit of measure: Kg	Number Analyzed	12 participants	12 participants	24 participants
		61.00 (10.05)	61.00 (8.55)	61.00 (9.12)
Blood Progesterone Level [1] Mean (Standard Deviation) Unit of measure: ng/ml	Number Analyzed	12 participants	12 participants	24 participants
		1.31 (0.85)	1.44 (0.77)	1.37 (0.79)
		[1] Measure Description: Blood progesterone level in Day -2		
Blood Estradiol Level [1] Mean (Standard Deviation) Unit of measure: pg/ml	Number Analyzed	12 participants	12 participants	24 participants
		2020.35 (998.36)	2464.33 (1144.19)	2262.52 (1078.94)
		[1] Measure Description: Blood Estradiol Level in day -2		
Blood LH level [1] Mean (Standard Deviation) Unit of measure: pg/ml	Number Analyzed	12 participants	12 participants	24 participants
		1.25 (0.45)	1.24 (0.91)	1.25 (0.70)
		[1] Measure Description: Blood LH level in day -2		

		Prolutex	Prontogest	Total
Endometrial Thickness [1] Mean (Standard Deviation) Unit of measure: mm	Number Analyzed	12 participants	12 participants	24 participants
		8.88 (1.98)	9.58 (1.61)	9.23 (1.80)
	[1] Measure Description: Endometrial Thickness in day 0			

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Predecidual Transformation
Measure Description	Histologic dating of the endometrium at day 5: early secretory phase, media secretory phase or late secretory phase
Time Frame	5 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	11
Predecidual Transformation Measure Type: Number Unit of measure: participants		
early secretory phase	1	2
media secretory phase	7	8

	Prolutex	Prontogest
late secretory phase	4	1

Statistical Analysis 1 for Predecidual Transformation

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3395
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

2. Primary Outcome Measure:

Measure Title	Decidualization of Stromal Cell
Measure Description	Rate of transformation of endometrial stromal fibroblasts into specialized secretory decidual cells (three categories: less than 25%, between 26% and 50%, and over 50%)
Time Frame	5 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	11
Decidualization of Stromal Cell Measure Type: Number Unit of measure: participants		
<25% of stromal cell	3	2
25-50% of stromal cell	3	7
> 50% of stromal cell	6	2

Statistical Analysis 1 for Decidualization of Stromal Cell

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1523
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

3. Primary Outcome Measure:

Measure Title	Endometrial Maturation Using Noyes' Criteria
Measure Description	Endometrial dating of luteal phase days according to the Noyes criteria
Time Frame	5 days

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	11
Endometrial Maturation Using Noyes' Criteria Mean (Standard Deviation) Unit of measure: days	9.08 (2.23)	7.64 (2.01)

Statistical Analysis 1 for Endometrial Maturation Using Noyes' Criteria

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	comparison between groups
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1189
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

4. Primary Outcome Measure:

Measure Title	Endometrial Gene Expression
Measure Description	Gene expression profile of endometrial
Time Frame	5 days

Analysis Population Description

We assessed the gene expression of 238 endometrial genes to detect differences in gene expression between treatments.

This analysis could not be performed in 1 patient of the prolutex group because of the poor quality of the sample collected

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	11	11
Overall Number of Units Analyzed Type of Units Analyzed: Endometrial genes	238	238
Endometrial Gene Expression Measure Type: Number Unit of measure: Endometrial genes		
differential expressed genes	28	28
the same trend of gene expression	210	210

5. Primary Outcome Measure:

Measure Title	Endometrial Gene Expression Difference
Measure Description	Genes with a significantly high gene expression difference (adj-p-value < 0.05, Fold Change>3)
Time Frame	5 days

Analysis Population Description

We assessed the expressed genes with a significantly high gene expression difference between treatments (adj-p-value < 0.05, Fold Change>3) This analysis could not be performed in 1 patient of the prolutex group because of the poor quality of the sample collected

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day

	Description
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	11	11
Overall Number of Units Analyzed Type of Units Analyzed: Endometrial genes	238	238
Endometrial Gene Expression Difference Measure Type: Number Unit of measure: Endometrial genes		
expressed genes with fold change > 3	4	4
expressed genes without or with fold change < 3	234	234

6. Secondary Outcome Measure:

Measure Title	Endometrial Thickness
Measure Description	Endometrial thickness measurement by means of transvaginal ultrasound.
Time Frame	5 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	12
Endometrial Thickness Mean (Standard Deviation) Unit of measure: mm	8.46 (2.66)	9.61 (1.24)

Statistical Analysis 1 for Endometrial Thickness

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2042
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Blood Estradiol Level
Measure Description	Blood estradiol level on the day of follicular puncture
Time Frame	day 0

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	11
Blood Estradiol Level Mean (Standard Deviation) Unit of measure: pg/mL	1384.06 (1122.80)	1208.58 (502.96)

Statistical Analysis 1 for Blood Estradiol Level

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6262
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

8. Secondary Outcome Measure:

Measure Title	Blood Progesterone Level
Measure Description	Blood progesterone level on the day of follicular puncture
Time Frame	day 0

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day

	Description
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	12
Blood Progesterone Level Mean (Standard Deviation) Unit of measure: ng/mL	14.40 (6.63)	10.92 (6.88)

Statistical Analysis 1 for Blood Progesterone Level

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2301
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Blood LH Level
Measure Description	Blood Luteinizing hormone level on the day of follicular puncture
Time Frame	day 0

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	12
Blood LH Level Mean (Standard Deviation) Unit of measure: pg/mL	2.32 (0.89)	2.75 (2.08)

Statistical Analysis 1 for Blood LH Level

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5118
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

10. Secondary Outcome Measure:

Measure Title	Blood Estradiol Level
Measure Description	Blood estradiol level 5 days after progesterone treatment
Time Frame	5 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	11
Blood Estradiol Level Mean (Standard Deviation) Unit of measure: pg/mL	257.88 (150.65)	246.45 (106.90)

Statistical Analysis 1 for Blood Estradiol Level

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8371
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

11. Secondary Outcome Measure:

Measure Title	Blood Progesterone Level
Measure Description	Blood progesterone level 5 days after progesterone treatment
Time Frame	5 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	11
Blood Progesterone Level Mean (Standard Deviation) Unit of measure: ng/mL	3.16 (1.00)	11.04 (5.21)

Statistical Analysis 1 for Blood Progesterone Level

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

12. Secondary Outcome Measure:

Measure Title	Blood LH Level
Measure Description	Blood Luteinizing hormone level 5 days after progesterone treatment
Time Frame	5 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	11
Blood LH Level Mean (Standard Deviation) Unit of measure: pg/mL	1.30 (0.60)	2.92 (5.36)

Statistical Analysis 1 for Blood LH Level

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3107
	Comments	[Not specified]
	Method	t-test, 2 sided
	Comments	[Not specified]

13. Secondary Outcome Measure:

Measure Title	Number of Participants With Side Effects During the Study
Measure Description	Number of Participants with side effects during the study"

Time Frame	5 days

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

Measured Values

	Prolutex	Prontogest
Overall Number of Participants Analyzed	12	12
Number of Participants With Side Effects During the Study Measure Type: Number Unit of measure: participants	5	4

Statistical Analysis 1 for Number of Participants With Side Effects During the Study

Statistical Analysis Overview	Comparison Group Selection	Prolutex, Prontogest
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Reported Adverse Events

Time Frame	5 days
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Prolutex	Subcutaneous progesterone Subcutaneous progesterone: subcutaneous progesterone 25 mg/day
Prontogest	Intramuscular progesterone Intramuscular progesterone: intramuscular progesterone 50 mg/day

All-Cause Mortality

	Prolutex		Prontogest	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total All-Cause Mortality	0/12 (0%)		0/12 (0%)	

Serious Adverse Events

	Prolutex		Prontogest	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	0/12 (0%)		0/12 (0%)	

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Prolutex		Prontogest	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	5/12 (41.67%)		4/12 (33.33%)	
General disorders				
Discomfort in injection site [1] *	3/12 (25%)	6	0/12 (0%)	0
Pain in injection site [2] *	0/12 (0%)	0	4/12 (33.33%)	6
Reproductive system and breast disorders				

	Prolutex		Prontogest	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Breast inflammation [3] *	2/12 (16.67%)	2	0/12 (0%)	0

* Indicates events were collected by non-systematic methods.

[1] Discomfort in injection site
[2] Pain in injection site
[3] Breast inflammation

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

All Principal Investigators ARE employed by the organization sponsoring the study.

Results Point of Contact:

Name/Official Title: Evelin Lara Molina
Organization: IVI Barcelona
Phone: +34 93 531 63 00 Ext: 27503
Email: Evelin.Lara@ivi.es