



## Clinical trial results:

**Randomized controlled trial comparing micronized progesterone (Amelgen ®) 400 mg BID versus 400 mg TID for luteal support in artificial vitrified/warmed single blastocyst transfer cycles with low progesterone on day of embryo transfer**

### Summary

EudraCT number	2020-004112-10
Trial protocol	BE
Global end of trial date	13 January 2025

### Results information

Result version number	v1 (current)
This version publication date	11 January 2026
First version publication date	11 January 2026
Summary attachment (see zip file)	Final Study Report (2020-004112-10_Final study report_PROTECTA.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	PROTECTA
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#### Additional study identifiers

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

Notes:

### Sponsors

Sponsor organisation name	University Hospital Ghent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	HIRUZ, Ghent University Hospital, +32 93320530, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ, Ghent University Hospital, +32 93320530, hiruz.ctu@uzgent.be

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	05 December 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	13 January 2025
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective is to investigate the effect of an increased dose of vaginal progesterone supplementation (Amelgen ® 400 mg BID vs Amelgen ® 400 mg TID) on the ongoing pregnancy (fetal heartbeat during TVUS between week 6 and 8 of pregnancy) rate for patients undergoing IVF or ICSI treatment with a suboptimal serum progesterone level (defined as <10 mcg/l) on the day of blastocyst transfer in an artificial prepared endometrium cycle.

Protection of trial subjects:

See attachment

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 April 2021
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	Belgium: 268
Worldwide total number of subjects	268
EEA total number of subjects	268

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)	268
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

See attachment

### Pre-assignment

Screening details:

See attachment

### Period 1

Period 1 title	Overall Study (overall period)
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Is this the baseline period?	Yes
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Allocation method	Randomised - controlled
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Blinding used	Not blinded
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Blinding implementation details:

See attachment

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Control Group
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Arm description:

See attachment

Arm type	Active comparator
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Investigational medicinal product name	Amelgen
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Vaginal gel
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Routes of administration	Vaginal use
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Dosage and administration details:

See attachment

<b>Arm title</b>	Intervention Group
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Arm description:

See attachment

Arm type	Active comparator
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Investigational medicinal product name	Amelgen
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Vaginal gel
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Routes of administration	Vaginal use
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Dosage and administration details:

See attachment

Investigational medicinal product name	Amelgen
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Investigational medicinal product code	
--	--

Other name	
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Pharmaceutical forms	Vaginal gel
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Routes of administration	Vaginal use
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Dosage and administration details:

See attachment

Number of subjects in period 1 <sup>[1]</sup>	Control Group	Intervention Group
Started	85	168
Completed	85	168

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Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: See attachment

## Baseline characteristics

## End points

### End points reporting groups

Reporting group title	Control Group
Reporting group description: See attachment	
Reporting group title	Intervention Group
Reporting group description: See attachment	

### Primary: Primary

End point title	Primary <sup>[1]</sup>
End point description: See attachment	
End point type	Primary
End point timeframe: During the study	

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: See attachment

End point values	Control Group	Intervention Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85 <sup>[2]</sup>	168 <sup>[3]</sup>		
Units: Heart				
number (not applicable)	85	168		

Notes:

[2] - 85

[3] - 168

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

During the study

Adverse event reporting additional description:

See attachment

Assessment type	Systematic
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### Dictionary used

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Dictionary name	MedDRA
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Dictionary version	0
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Frequency threshold for reporting non-serious adverse events: 0 %

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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: See attachment

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported