



Clinical trial results:

Impact of luteal phase support with vaginal progesterone on the clinical pregnancy rate in IUI cycles stimulated with gonadotrophins: a prospective randomized multicentre study.

Summary

EudraCT number	2010-023867-17
Trial protocol	BE
Global end of trial date	22 October 2015

Results information

Result version number	v1 (current)
This version publication date	14 February 2021
First version publication date	14 February 2021
Summary attachment (see zip file)	Publication (2010-023867-17 publication.pdf)

Trial information

Trial identification

Sponsor protocol code	S52775
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01826747
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UZLeuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Karen Peeraer, UZLeuven, +32 16343650, karen.peeraer@uzleuven.be
Scientific contact	Karen Peeraer, UZLeuven, +32 16343650, karen.peeraer@uzleuven.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	22 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 October 2015
Global end of trial reached?	Yes
Global end of trial date	22 October 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Test the hypothesis that luteal phase support with vaginal progesterone leads to a higher clinical pregnancy rate when compared to no luteal phase support in a program of intrauterine insemination after controlled ovarian stimulation with gonadotrophins

Protection of trial subjects:

No measurements were taken. Study did not cause additional pain or distress.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2011
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: 393
Worldwide total number of subjects	393
EEA total number of subjects	393

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)	393
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All couples with an indication for intrauterine insemination (IUI) such as unexplained infertility, mild male factor infertility, or minimal/mild endometriosis were eligible for this study during their first IUI cycle. Before their inclusion in the study, all couples underwent a complete infertility evaluation.

Pre-assignment

Screening details:

first IUI cycle

Physical examination, medical history check

serum hormone assay between day 2 and 5 of menstrual cycle

pelvic ultrasound

assessment of

tubal patency either by hysterosalpingography or laparoscopy, and semen analysis

<43 years old, BMI = <30

at least

one patent tube

partner sperm motile of ≥ 5 million

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	control group without luteal phase support

Arm description:

control group: standard of care intrauterine insemination

Arm type	No intervention
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No investigational medicinal product assigned in this arm

Arm title	study group with luteal phase support
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Arm description:

study group with luteal phase support. Vaginal progesterone gel used

Arm type	Experimental
Investigational medicinal product name	Crinone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Vaginal use

Dosage and administration details:

once daily in the morning starting on the day after IUI until the time of pregnancy test (b-hCG) about 15 days after IUI. Crinone was administered by an applicator that delivered 1.125 g of vaginal gel containing 90 mg of progesterone.

Number of subjects in period 1	control group without luteal phase support	study group with luteal phase support
Started	191	202
Completed	177	187
Not completed	14	15
Physician decision	6	3
Pregnancy	5	7
patient decision	2	4
Protocol deviation	1	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	393	393	
Age categorical			
Female subjects age: 18-42 year			
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)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Female 18-42 years	393	393	
Gender categorical			
Units: Subjects			
Female	393	393	
Male	0	0	

End points

End points reporting groups

Reporting group title	control group without luteal phase support
Reporting group description: control group: standard of care intrauterine insemination	
Reporting group title	study group with luteal phase support
Reporting group description: study group with luteal phase support. Vaginal progesterone gel used	

Primary: Clinical pregnancy rate

End point title	Clinical pregnancy rate ^[1]
End point description:	

End point type	Primary
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End point timeframe:

Primary endpoint is clinical pregnancy rate. 34 of the 202 patients in the study group became pregnant (16.8%). 21 of the 191 patients in the control group became pregnant (11%)

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: not specified in publication

End point values	control group without luteal phase support	study group with luteal phase support		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	191	202		
Units: 34	21	34		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Safety was not an endpoint of the study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.0
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Frequency threshold for reporting non-serious adverse events: 0 %

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: adverse events not collected

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/27565253>