Clinical trial results:
A single centre open-label randomised controlled trial of long term pituitary down-regulation before in vitro fertilisation for women with endometriosis: a pilot study

Summary

EudraCT number	2012-004954-27
Trial protocol	GB
Global end of trial date	07 November 2013

Results information

Result version number	v1 (current)
This version publication date	21 February 2019
First version publication date	21 February 2019
Summary attachment (see zip file)	Final report eraly termination (final report on study.docx)

Trial information

Trial identification

Sponsor protocol code	8668

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of Oxford
Sponsor organisation address	Boundary Brook House, Churchill Drive, Oxford, United Kingdom, OX3 7GB
Public contact	Research Services, Clinical Trials and Research Governance, 44 1865616484,
Scientific contact	Research Services, Clinical Trials and Research Governance, 44 1865616484,

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	07 November 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 November 2013
Global end of trial reached?	Yes
Global end of trial date	07 November 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to determine if pre-treatment with oral contraceptives improves IVF or IVF-ICSI success rates (i.e. live birth rates) in patients who suffer from endometriosis.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2013
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	United Kingdom: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	5
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study participants were women undertaking IVF or IVF-ICSI cycles at the Oxford Fertility Unit between January 2013 (to January 2015).

Pre-assignment

Screening details:

Infertile women with endometriosis undergoing IVF or IVF-ICSI

Period 1

Period 1 title	Baseline (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

Arm description:

No intervention

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	COCP

Arm description:

8 weeks of COCP before IVF cycle

Arm type	Experimental
Investigational medicinal product name	Microgynon 30 (COCP)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Microgynon, Levonorgestrel/Ethinylestradiol 150/30mcg daily for 8 weeks

Number of subjects in period 1	Control	COCP
Started	2	3
Completed	2	3

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	5	5	
Age categorical			
Women aged between 18 and 39 years of age			
Units: Subjects			
all participants	5	5	
Gender categorical Units: Subjects			
Female	5	5	

End points

End points reporting groups

Reporting group title	Control
Reporting group description:	
No intervention	
Reporting group title	COCP
Reporting group description:	
8 weeks of COCP before IVF cycle	

Primary: Live Birth Rate

End point title	Live Birth Rate[1]
End point description:	
End point type	Primary
End point timeframe:	
40 weeks	

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: 5 participants. Early termination of the study. No statistical analyses were performed.

End point values	Control	COCP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[2]	3[3]		
Units: Live Births (number)	0	0		

Notes:

[2] - No analysis done for this trial

[3] - No analysis done for this trial

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: between January 2013 to November 2013.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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

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: 5 participants. Early termination of the study. No adverse events.

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.

In November 2013 the decision was made for early termination of the study. Despite our best efforts, only 5 women had been recruited and this rate of recruitment is unlikely to increase significantly in the future. Clearly no evaluation can be made f

Notes: