Clinical trial results:
The effect of metformin co-treatment in hormone-replacement frozen embryo replacement cycles in women with polycystic ovary syndrome.

Summary

EudraCT number	2009-017245-64
Trial protocol	GB
Global end of trial date	13 May 2013

Results information

Result version number	v1 (current)
This version publication date	21 October 2017
First version publication date	21 October 2017

Trial information

Trial identification

Sponsor protocol code	OG09/9146

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Leeds Teaching Hospitals
Sponsor organisation address	34 Hyde Terrace, Leeds, United Kingdom, LS9 6LN
Public contact	Professor Adam Balen, Leeds Teaching Hospitals, 0113 3926473, leedsth-tr.sponsorqa@nhs.net
Scientific contact	Professor Adam Balen, Professor Adam Balen, 0113 2063125, adam.balen@nhs.net

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	13 May 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 May 2013
Global end of trial reached?	Yes
Global end of trial date	13 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Outcome Measure:
Live birth rate per frozen embryo replacement treatment cycle

Protection of trial subjects:

GCP & reviewed by ethics & MRHA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2010
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: 33
Worldwide total number of subjects	33
EEA total number of subjects	33

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)	33
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruited 33 patients

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	33
Number of subjects completed	

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Metformin

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Metformin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

850mg tablets twice daily

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

one tablet twice daily

Number of subjects in period 1	Metformin	Placebo
Started	16	17
Completed	15	17
Not completed	1	0
Adverse event, non-fatal	1	-

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	33	33	
Age categorical			
women of reproductive age between 23-40 years old			
Units: Subjects			
Adults (18-64 years)	33	33	
Gender categorical			
women undergoing Frozen embryo transfer cycle			
Units: Subjects			
Female	33	33	

Subject analysis sets

Subject analysis set title	metformin
Subject analysis set type	Per protocol

Subject analysis set description:
Per protocol

Subject analysis set title	Standard treatment per protocol
Subject analysis set type	Per protocol

Subject analysis set description:
Per protocol

Reporting group values	metformin	Standard treatment per protocol	
Number of subjects	16	17	
Age categorical			
women of reproductive age between 23-40 years old			
Units: Subjects			
Adults (18-64 years)	16	17	
Gender categorical			
women undergoing Frozen embryo transfer cycle			
Units: Subjects			
Female	16	17	

End points

End points reporting groups

Reporting group title	Metformin
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	metformin
Subject analysis set type	Per protocol
Subject analysis set description: Per protocol	
Subject analysis set title	Standard treatment per protocol
Subject analysis set type	Per protocol
Subject analysis set description: Per protocol	

Primary: clinical pregnancy

End point title	clinical pregnancy
End point description:	
End point type	Primary
End point timeframe: 30 months	

End point values	Metformin	Placebo	metformin	Standard treatment per protocol
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	16	17	16	17
Units: percentage	16	17	16	17

Statistical analyses

Statistical analysis title	Clinical pregnancy rate
Comparison groups	Placebo v Metformin
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	NCRI Common Toxicity
Dictionary version	4

Reporting groups	
Reporting group title	Gi effects

Reporting group description: -

Serious adverse events	Gi effects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Gi effects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)		
Gastrointestinal disorders			
GI side effect			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 March 2010	Protocol amended

Notes:

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.

No

Notes: