Clinical trial results:
Effect of the combined treatment with myo-inositol and metformin on the phenotype of the polycystic ovary syndrome: a pilot study

Summary

EudraCT number	2008-006991-31
Trial protocol	IT
Global end of trial date	31 January 2011

Results information

Result version number	v1 (current)
This version publication date	13 October 2022
First version publication date	13 October 2022

Trial information

Trial identification

Sponsor protocol code	143/2008/U/Sper

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IRCCS n- Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi
Sponsor organisation address	Via Albertoni 15, Bologna, Italy, 40138
Public contact	Alessandra Gambineri , IRCCS Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi,UO Endocrinologia, 0039 3477738178, alessandra.gambiner3@unibo.it
Scientific contact	Alessandra Gambineri , IRCCS Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi,UO Endocrinologia, 0039 3477738178, alessandra.gambiner3@unibo.it

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	31 December 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2009
Global end of trial reached?	Yes
Global end of trial date	31 January 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary aim of the study is to evaluate the impact of 6 months treatment with myo-inositol and metformin on insulin resistance of women with the polycystic ovary syndrome (PCOS) when compared with myo-inositol or metformin alone

Protection of trial subjects:

Yes, by specific insurance

Background therapy:

none

Evidence for comparator:

Literature

Actual start date of recruitment	19 June 2009
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	Italy: 45
Worldwide total number of subjects	45
EEA total number of subjects	45

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)	45
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment according to a list of randomization

Pre-assignment

Screening details:

Screening performed according to inclusion and exclusion criteria

Pre-assignment period milestones

Number of subjects started	45
Number of subjects completed	45

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	Myo+Met

Arm description:

Myo-inositol 4g/die plus Metformin 1700mg/die

Arm type	No IMP
Investigational medicinal product name	Myo-inositol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral/rectal suspension in sachet
Routes of administration	Oral use

Dosage and administration details:

4g/die

Investigational medicinal product name	Metformin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pastille, Pillules
Routes of administration	Oral use

Dosage and administration details:

1700mg/die

Arm title	Myo-inositol

Arm description:

Myo-inositol 4g/die

Arm type	NO IMP

Investigational medicinal product name	Myo-inositol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral solution, Powder for oral suspension in sachet
Routes of administration	Oral use

Dosage and administration details:

4g/die

Arm title	Metformin

Arm description:

Metformin 1700mg/die

Arm type	NO IMP

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Myo+Met	Myo-inositol	Metformin
Started	15	15	15
Completed	14	15	14
Not completed	1	0	1
Adverse event, not serious	1	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Myo+Met
Reporting group description: Myo-inositol 4g/die plus Metformin 1700mg/die	

Reporting group title	Myo-inositol
Reporting group description: Myo-inositol 4g/die	

Reporting group title	Metformin
Reporting group description: Metformin 1700mg/die	

Reporting group values	Myo+Met	Myo-inositol	Metformin
Number of subjects	15	15	15
Age categorical			
Adults (18-64 years)			
Units: Subjects			
Adults (18-64 years)	15	15	15
Age continuous			
Units: years			
arithmetic mean	23.4	25.5	24.3
standard deviation	± 4.9	± 3.9	± 4
Gender categorical			
female			
Units: Subjects			
female	15	15	15
Glucose			
fasting blood glucose			
Units: mg/dl			
arithmetic mean	82.5	86.3	82.5
standard deviation	± 7.6	± 8.2	± 7.6
blood insulin			
fasting blood insulin			
Units: µUI/mL			
arithmetic mean	9.72	8.38	9.54
standard deviation	± 3.23	± 3.89	± 4.47

Reporting group values	Total		
Number of subjects	45		
Age categorical			
Adults (18-64 years)			
Units: Subjects			
Adults (18-64 years)	45		

Age continuous Units: years arithmetic mean standard deviation	- 		
Gender categorical			
female			
Units: Subjects			
female	45		
Glucose			
fasting blood glucose			
Units: mg/dl arithmetic mean standard deviation	- 		
blood insulin			
fasting blood insulin			
Units: µUI/mL arithmetic mean standard deviation	- 		

End points

End points reporting groups

Reporting group title	Myo+Met
Reporting group description: Myo-inositol 4g/die plus Metformin 1700mg/die	

Reporting group title	Myo-inositol
Reporting group description: Myo-inositol 4g/die	

Reporting group title	Metformin
Reporting group description: Metformin 1700mg/die	

Primary: blood glucose

End point title	blood glucose
End point description: fasting blood glucose	
End point type	Primary
End point timeframe: 6 months	

End point values	Myo+Met	Myo-inositol	Metformin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14[1]	15	14[2]	
Units: mmol/dl				
arithmetic mean (standard deviation)	82.5 (± 7.6)	86.3 (± 08.2)	83.9 (± 10.1)	

Notes:
[1] - one drop out
[2] - one drop out

Statistical analyses

Statistical analysis title	ANOVA
Comparison groups	Myo+Met v Myo-inositol v Metformin
Number of subjects included in analysis	43
Analysis specification	Post-hoc
Analysis type	non-inferiority[3]
P-value	≥ 1 [4]
Method	ANOVA

Notes:
[3] - TWO-WAY ANOVA (Time x treatment)
[4] - not significant

Primary: blood insulin	
End point title	blood insulin
End point description: fasting blood insulin	
End point type	Primary
End point timeframe: 6 months	

End point values	Myo+Met	Myo-inositol	Metformin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14[5]	15	14[6]	
Units: µUI/ml				
arithmetic mean (standard deviation)	8.28 (± 3.89)	9.54 (± 4.47)	9.72 (± 3.23)	

Notes:

[5] - one drop out

[6] - one drop out

Statistical analyses

Statistical analysis title	ANOVA
Comparison groups	Myo+Met v Myo-inositol v Metformin
Number of subjects included in analysis	43
Analysis specification	Post-hoc
Analysis type	non-inferiority[7]
P-value	≥ 1 [8]
Method	ANOVA

Notes:

[7] - TWO-WAY ANOVA (Time x treatment)

[8] - not significant

Adverse events

Adverse events information	
Timeframe for reporting adverse events: one month	
Adverse event reporting additional description: gastrointestinal disease	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	arm1
Reporting group description: -	
Reporting group title	arm2
Reporting group description: -	
Reporting group title	arm 3
Reporting group description: -	

Serious adverse events	arm1	arm2	arm 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 0.04 %

Non-serious adverse events	arm1	arm2	arm 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	14	15	14

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