



Clinical trial results:

Clinical Trial crossed athletic population according UGT2B17 polymorphism. Impact on the steroid profile

Summary

EudraCT number	2013-005135-24
Trial protocol	ES
Global end of trial date	16 June 2015

Results information

Result version number	v1 (current)
This version publication date	10 February 2022
First version publication date	10 February 2022

Trial information

Trial identification

Sponsor protocol code	ECDOPDEP2013
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Fundacion para la investigación biomedica del hospital clínico San Carlos
Sponsor organisation address	Calle del Prof Martín Lagos, s/n, , madrid, Spain,
Public contact	UCICEC, fundacion para la investigación biomedica del hospital clínico San Carlos, 0034 9133030003793, fibucicec.hcsc@salud.madrid.org
Scientific contact	UCICEC, fundacion para la investigación biomedica del hospital clínico San Carlos, 0034 9133030003793, fibucicec.hcsc@salud.madrid.org

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	Interim
Date of interim/final analysis	16 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 June 2015
Global end of trial reached?	Yes
Global end of trial date	16 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Contrast variability of steroid profile during at least periods of time of two months versus the model developed from 2 days based model.

Follow development of mathematical model implemented to characterized steroid profile during long periods of time.

Protection of trial subjects:

This is a non-commercial study financed by the National R&D&I Plan for Non-Oriented Research. Once approved, an insurance policy will be taken out.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 May 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects**Subjects enrolled per country**

Country: Number of subjects enrolled	Spain: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	12
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Healthy athletes between 18 and 55 years of age, of both sexes, from different sports specialties who have completed the previous study (DEP2009-14788-C01-C03).

Period 1

Period 1 title	PRE
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Blinding implementation details:

the results of a triple-blind randomized placebo-controlled crossover trial

Arms

Arm title	placebo
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Arm description:

3 groups:
del/del n=4;
del/ins n=4,
ins/ins or WT n=4

Arm type	Active comparator
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

placebo

Number of subjects in period 1	placebo
Started	12
Completed	12

Period 2

Period 2 title	POST
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Arms

Arm title	testex
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Arm description:

3 groups:

del/del n=4;

del/ins n=4,

ins/ins or WT n=4

Arm type	Experimental
Investigational medicinal product name	TESTEX ELMU PROLONGATUM
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

TESTEX ELMU PROLONGATUM 2 ml with Testosterone Cyclopentyl Propionate 250 mg (injectable).

Number of subjects in period 2	testex
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	placebo
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Reporting group description:

3 groups:

del/del n=4;

del/ins n=4,

ins/ins or WT n=4

Reporting group values	placebo	Total	
Number of subjects	12	12	
Age categorical			
Units: Subjects			
Adults (18-64 years)	12	12	
Age continuous			
Units: years			
arithmetic mean	39.9		
standard deviation	± 11.2	-	
Gender categorical			
Units: Subjects			
Male	12	12	

End points

End points reporting groups

Reporting group title	placebo
Reporting group description: 3 groups: del/del n=4; del/ins n=4, ins/ins or WT n=4	
Reporting group title	testex
Reporting group description: 3 groups: del/del n=4; del/ins n=4, ins/ins or WT n=4	

Primary: Contrast variability of steroid profile during at least periods of time of two months versus the model developed from 2 days based model.

End point title	Contrast variability of steroid profile during at least periods of time of two months versus the model developed from 2 days based model.
End point description:	
End point type	Primary
End point timeframe: Forty urine samples were collected from each participant over 7 months	

End point values	placebo	testex		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: testosterone/epitestosterone(T/E) ratio				
number (not applicable)	12	12		

Statistical analyses

Statistical analysis title	Steroid profile characterization
Comparison groups	placebo v testex
Number of subjects included in analysis	24
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.05
Method	Regression, Linear

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

During the course of the study there have been no withdrawals from the study, no serious adverse events, no major protocol deviations and no deaths during the study period.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	unkwon
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Dictionary version	unkwon
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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: no non-serious adverse events due to lack of recruitment

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