Clinical trial results:
Use of tramadol in healthy volunteers.
Effects on physical performance and sustained attention in cycling.

Summary

EudraCT number	2015-005056-96
Trial protocol	ES
Global end of trial date	02 February 2017

Results information

Result version number	v1 (current)
This version publication date	24 June 2021
First version publication date	24 June 2021
Summary attachment (see zip file)	Results report (Informe final resultados TRAWADA2015.pdf) Dataset Cohort 1 (Cohort1.xlsx) Data Set Cohort 2 (Cohort2.xlsx)

Trial information

Trial identification

Sponsor protocol code	TRAWADA2015

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Centro de investigación mente cerebro y comportamiento
Sponsor organisation address	Campus de la Cartuja s/n, Granada, Spain, 18011
Public contact	Emilio García Cabrera, Delos Clinical, 0034 655843699, emiliogcabrera@delosclinical.com
Scientific contact	Emilio García Cabrera, Delos Clinical, 0034 655843699, emiliogcabrera@delosclinical.com

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	28 February 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 February 2017
Global end of trial reached?	Yes
Global end of trial date	02 February 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the effect of an acute dose of tramadol compared to placebo, in the physical and cognitive performance in cyclists

Protection of trial subjects:

Incidencia de acontecimientos adversos (AA)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 July 2016
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	Spain: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	60
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	60
Number of subjects completed	60

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?	No
Arm title	Tramadol

Arm description:

Capsulas de gelatina dura, numero 0 de color rojo que contienen 2 capsulas de 50 mg de tramadol EFG.

Arm type	Experimental
Investigational medicinal product name	TRAMADOL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsulas de gelatina dura, numero 0 de color rojo que contienen 2 capsulas de 50 mg de tramadol EFG.

Arm title	Placebo

Arm description:

Capsulas de gelatina dura, numero 0 de color rojo que contienen 100mg de hidroxipropilmetilcelulosa

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

Dosage and administration details:

Cápsulas de gelatina dura, numero 0 de color rojo que contienen 100mg de hidroxipropilmetilcelulosa

Number of subjects in period 1	Tramadol	Placebo
Started	60	60
Completed	57	57
Not completed	3	3
Adverse event, non-fatal	2	2
Lost to follow-up	1	1

Baseline characteristics

Reporting groups	
Reporting group title	overall trial
Reporting group description:	
Baseline period	

Reporting group values	overall trial	Total	
Number of subjects	60	60	
Age categorical Units: Subjects			
Adults (18-64 years)	60	60	
Age continuous Units: years			
arithmetic mean	25		
standard deviation	± 6	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	50	50	

Subject analysis sets	
Subject analysis set title	Cohorte 1
Subject analysis set type	Per protocol
Subject analysis set description:	
Healthy volunters	
Subject analysis set title	Cohorte 2
Subject analysis set type	Full analysis
Subject analysis set description:	
Professional cyclist	

Reporting group values	Cohorte 1	Cohorte 2	
Number of subjects	28	29	
Age categorical Units: Subjects			
Adults (18-64 years)	30	30	
Age continuous Units: years			
arithmetic mean	25	25	
standard deviation	± 7	± 5	
Gender categorical Units: Subjects			
Female	10	0	
Male	20	30	

End points

End points reporting groups

Reporting group title	Tramadol
Reporting group description:	
Capsulas de gelatina dura, numero 0 de color rojo que contienen 2 capsulas de 50 mg de tramadol EFG.	
Reporting group title	Placebo
Reporting group description:	
Capsulas de gelatina dura, numero 0 de color rojo que contienen 100mg de hidroxipropilmetilcelulosa	
Subject analysis set title	Cohorte 1
Subject analysis set type	Per protocol
Subject analysis set description:	
Healthy volunters	
Subject analysis set title	Cohorte 2
Subject analysis set type	Full analysis
Subject analysis set description:	
Professional cyclist	

Primary: Rendimiento físico

End point title	Rendimiento físico
End point description:	
La evaluación de rendimiento físico, se realizará mediante la diferencia de medias del umbral de potencia funcional (UPF). Se ha definido como la potencia media más alta que puede mantener durante 1 hora aproximadamente (Allen & Coggan, 2010). Cuando se mide correctamente, UPF es una intensidad que es similar al umbral de lactato en sangre, que a su vez se ha encontrado que es altamente predictivo del rendimiento en eventos y distancias de resistencia (Faude et al., 2009). Se evaluará la diferencia de la potencia media entre las dos condiciones que presentará el paciente, con tratamiento de tramadol y de placebo.	
End point type	Primary
End point timeframe:	
30 min	

End point values	Cohorte 1	Cohorte 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	29		
Units: UPF	28	29		

Statistical analyses

Statistical analysis title	Main objective analysis
Comparison groups	Cohorte 1 v Cohorte 2

Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

30 days

Adverse event reporting additional description:

pacientes fueron de la cohorte 1 (30%), y 4 (13,3%) fueron de la cohorte 2. Del total de 27 acontecimientos adversos, todos (100%) fueron acontecimientos adversos no graves. El 96,3% (26/27) se produjeron en los pacientes cuando tomaron tramadol y fueron relacionados con la medicación a estudio.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	7

Reporting groups

Reporting group title	Cohorte 1
Reporting group description: -	
Reporting group title	Cohorte 2

Reporting group description: -

Serious adverse events	Cohorte 1	Cohorte 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)	0 / 29 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Cohorte 1	Cohorte 2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 28 (28.57%)	3 / 29 (10.34%)	
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	7 / 28 (25.00%)	3 / 29 (10.34%)	
occurrences (all)	7	3	
Somnolence			

subjects affected / exposed	4 / 28 (14.29%)	0 / 29 (0.00%)	
occurrences (all)	4	0	
Headache			
subjects affected / exposed	2 / 28 (7.14%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
General disorders and administration site conditions			
Malaise			
subjects affected / exposed	5 / 28 (17.86%)	1 / 29 (3.45%)	
occurrences (all)	5	1	
Abdominal pain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	2 / 28 (7.14%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Dry mouth			
subjects affected / exposed	1 / 28 (3.57%)	0 / 29 (0.00%)	
occurrences (all)	1	0	

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