Clinical trial results:
"Efecto del ARA-II Olmesartan sobre el metabolismo del potasio en pacientes con insuficiencia renal crónica"

Summary

EudraCT number	2008-002191-98
Trial protocol	ES
Global end of trial date	28 November 2013

Results information

Result version number	v1 (current)
This version publication date	19 December 2021
First version publication date	19 December 2021

Trial information

Trial identification

Sponsor protocol code	PREVARENAL-08

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	VHIR
Sponsor organisation address	Passeig Vall Hebron 119-129, Barcelona, Spain, 08035
Public contact	Joaquin Lopez-Soriano, VHIR, joaquin.lopez.soriano@vhir.org
Scientific contact	Eugenia Espinel, VHIR, eespinel@vhebron.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	30 December 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 November 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the effects of administration of an inhibitor of angiotensin converting enzyme with an atagonist of AT1 receptors of angiotensin, on plasma potassium levels.
Comparar el efecto de la administración de un inhibidor del enzima de conversión del angiotensina con un antagonista de los receptores AT1 de la angiotensina, sobre los niveles de potasio plasmáticos.

Protection of trial subjects:

Each patient was visited 10 times throughout the study to avoid severe complications. Routien analysis at each visit included cereatinine, potassium, sodium and osmolarity in serum, and albumin, creatinine, sodium and potassium in urine.
No patient with arterial stenosis was included.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 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	Spain: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Stage 3 CKD patients with stable condition, GFR 30-60 ml/min/1.73 m2, aged 18-75 years, serum potassium concentration <5 mmol/L, blood pressure 130/80 -180/100 mmHg were considered for inclusion. Use of calcium channel blockers or alpha-adrenergic blockers were not exclusion criteria. 4 patients were excluded for not following a salt balanced diet

Period 1

Period 1 title	First treatment OLM ENA
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Arm title	OLMERSATAN

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Olmersatan
Investigational medicinal product code	
Other name	Openvas
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg orally daily for 1 week

Number of subjects in period 1	OLMERSATAN
Started	30
Completed	27
Not completed	3
Protocol deviation	3

Period 2

Period 2 title	Second treatment OLM ENA
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Arm title	Enalapril
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Enalapril
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg orally daily for 1 week

Number of subjects in period 2	Enalapril
Started	27
Completed	20
Not completed	7
Protocol deviation	7

Baseline characteristics

Reporting groups	
Reporting group title	OLMERSATAN

Reporting group description: -

Reporting group values	OLMERSATAN	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
median	60.2		
standard deviation	± 12.9	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	20	20	

End points

End points reporting groups	
Reporting group title	OLMERSATAN
Reporting group description: -	
Reporting group title	Enalapril
Reporting group description: -	

Primary: Plasma Potassium Increase

End point title	Plasma Potassium Increase
End point description:	
End point type	Primary
End point timeframe:	
12 weeks	

End point values	OLMERSATAN	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	20		
Units: nmol/l				
number (not applicable)	0.24	0.30		

Statistical analyses

Statistical analysis title	Potassium increase
Comparison groups	OLMERSATAN v Enalapril
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.05
Method	ANOVA

Primary: Microalbuminuria decrease

End point title	Microalbuminuria decrease
End point description:	
End point type	Primary
End point timeframe:	
12 weeks	

End point values	OLMERSATAN	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	20		
Units: percent				
number (not applicable)	23	29		

Statistical analyses

Statistical analysis title	Microalbuminuria
Comparison groups	OLMERSATAN v Enalapril
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.05
Method	ANOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 12 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups	
Reporting group title	Total adverse events

Reporting group description: -

Serious adverse events	Total adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Total adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 30 (13.33%)		
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	4 / 30 (13.33%)		
occurrences (all)	4		

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.

Stage 3 CKD patients treated with these drugs should also be controlled at the end of month 1 and 2. After that point, patients should be controlled at the periods recommended at guidelines, to follow-up stable stage 3 CKD patients, and also when a c

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/23915518