Clinical trial results:
ESTUDIO DE LA EFICACIA DE BOSENTAN EN LA MODULACIÓN DE LA RESPUESTA INFLAMATORIA Y DE LA CICATRIZACIÓN EN PACIENTES QUEMADOS

Summary

EudraCT number	2010-023822-19
Trial protocol	ES
Global end of trial date	30 June 2017

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	bosentan2010

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, +34 934894779, joaquin.lopez.soriano@vhir.org
Scientific contact	Juan Pedro Barret Nerín, VHIR, jpbarret@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 June 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 June 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. Estudiar el efecto de Bosentan en la modulación de la respuesta inflamatoria en los pacientes quemados
2. Estudiar el efecto de Bosentan en la modulación de la cicatrización de los pacientes quemados
3. Determinar la seguridad del tratamiento con Bosentan en los pacientes quemados

Protection of trial subjects:

Standard procedures of the burn unit. Tewamenter was used to asses skin cicatrization

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2013
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:

Patients were screened at Burns Unit at Vall Hebron Hospital (Barcelona). A daily assesment of patients was performed.

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	Bosentan

Arm description: -

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

Dosage and administration details:

125 mg orally, daily use

Arm title	Control no treatment

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Bosentan	Control no treatment
Started	7	5
Completed	6	4
Not completed	1	1
Consent withdrawn by subject	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	12	12	
Age categorical Units: Subjects			
Adults (18-64 years)	12	12	
Gender categorical Units: Subjects			
Female	4	4	
Male	8	8	

End points

End points reporting groups	
Reporting group title	Bosentan
Reporting group description: -	
Reporting group title	Control no treatment
Reporting group description: -	

Primary: Percentage burn	
End point title	Percentage burn
End point description:	
End point type	Primary
End point timeframe:	
6 months follow-up	

End point values	Bosentan	Control no treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	4		
Units: percent				
arithmetic mean (standard deviation)	37.40 (± 14.10)	32.75 (± 10.21)		

Statistical analyses

Statistical analysis title	Percentage burn
Comparison groups	Bosentan v Control no treatment
Number of subjects included in analysis	10
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.05
Method	t-test, 2-sided

Secondary: Days hospitalization	
End point title	Days hospitalization
End point description:	
End point type	Secondary
End point timeframe:	
60 days follow-up	

End point values	Bosentan	Control no treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	4		
Units: day				
arithmetic mean (standard deviation)	25.60 (± 7.02)	35.75 (± 9.39)		

Statistical analyses

Statistical analysis title	Days at hospital
Comparison groups	Bosentan v Control no treatment
Number of subjects included in analysis	10
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: 60 days follow-up	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1
Reporting groups	
Reporting group title	Bosentan
Reporting group description: -	
Reporting group title	Control no treatment
Reporting group description: -	

Serious adverse events	Bosentan	Control no treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 4 (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: 5 %

Non-serious adverse events	Bosentan	Control no treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	
Blood and lymphatic system disorders			
Hypotension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	1 / 6 (16.67%)	0 / 4 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 March 2013	Changes in consent information protocol because of safety issues
18 December 2013	Changes in inclusion criteria

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.

Small number of patients preclude from obtaining robust conclusions. However, Bosentan use is safe.

Notes: