Clinical trial results:
Etude préliminaire de l’efficacité d’un 1 bloquant (la prazosine) en prévention de la survenue d’un état de stress post-traumatique chez des patients présentant un état de stress aigu.

Summary

EudraCT number	2016-004653-32
Trial protocol	FR
Global end of trial date	30 March 2020

Results information

Result version number	v1 (current)
This version publication date	22 December 2021
First version publication date	22 December 2021

Trial information

Trial identification

Sponsor protocol code	69HCL16_0628

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Hospices Civils de Lyon
Sponsor organisation address	3, Quai des Célestins, LYON, France, 69002
Public contact	Direction de la Recherche Clinique , Hospices Civils de Lyon, +33 472406 842, cecile.riera@chu-lyon.fr
Scientific contact	Direction de la Recherche Clinique , Hospices Civils de Lyon, +33 472406 842, cecile.riera@chu-lyon.fr

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	15 August 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Tester l'efficacité de la prazosine en cure courte chez des patients présentant un ESA afin de prévenir le développement d'un ESPT à 6 mois évalué par l'échelle CAPS.

Protection of trial subjects:

Respect des critères d'éligibilité et des procédures du protocole ; notification des EI et EIG au promoteur ; assurance qualité (monitoring) assurée par le promoteur sur l'ensemble des dossiers patients

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2017
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	France: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were screened either during their visit to an emergency department or during hospitalization or consultation or at the medico-judicial unit (for juridical procedure following an assault or an accident). If an ASD was diagnosed, patients were referred to the study inclusion consultation between 3 and 7 days after the event.

Pre-assignment

Screening details:

Patients were screened either during their visit to an emergency department, or during hospitalization or consultation at the Hospices Civils de Lyon, or at the medico-judicial unit. If an ASD was diagnosed, patients were referred to the study inclusion consultation between 3 and 7 days after the event.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Prazosin, ALPRESS® LP 2,5 et 5 mg

Arm description:

Patients included in this study will be adults with acute stress as a result of a direct experience traumatic event. They will be treated with Prazosin, ALPRESS® LP 2,5 et 5 mg during 28 days.

Arm type	Experimental
Investigational medicinal product name	ALPRESS XR 2.5 mg (Prazozine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

-PERIOD 1 (D0-D7): 1 tablet of ALPRESS XR 2.5 mg (Prazozine) at bedtime for 7 days

Investigational medicinal product name	ALPRESS XR 5 mg (Prazozine)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

- PERIOD 2 (D8-D27): 1 morning tablet of ALPRESS XR 5 mg (Prazozine) at bedtime for 21 days

Number of subjects in period 1	Prazosin, ALPRESS® LP 2,5 et 5 mg
Started	15
Completed	8
Not completed	7
Lost to follow-up	7

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	15	15	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	15	15	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
The mean age was 30,2 years old and the median age 26 years old with a range from 18 to 48 years old.			
Units: years			
arithmetic mean	30.2		
full range (min-max)	18 to 48	-	
Gender categorical Units: Subjects			
Female	7	7	
Male	8	8	

End points

End points reporting groups

Reporting group title	Prazosin, ALPRESS® LP 2,5 et 5 mg

Reporting group description:

Patients included in this study will be adults with acute stress as a result of a direct experience traumatic event. They will be treated with Prazosin, ALPRESS® LP 2,5 et 5 mg during 28 days.

Primary: Presence of PTSD

End point title	Presence of PTSD[1]

End point description:

End point type	Primary

End point timeframe:

6 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses have been conducted for this primary end point ; only descriptive analyses have been performed.

End point values	Prazosin, ALPRESS® LP 2,5 et 5 mg			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: number of events	2			

Attachments (see zip file)	Flowchart PRAZOSTRESS.docx

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 7 days, 14 days, 1 month, 3 months, 6 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups	
Reporting group title	ALPRESS XR 2.5 or 5 mg (Prazozine)

Reporting group description: -

Serious adverse events	ALPRESS XR 2.5 or 5 mg (Prazozine)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	ALPRESS XR 2.5 or 5 mg (Prazozine)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 15 (60.00%)		
Nervous system disorders			
Vertigo positional			
subjects affected / exposed	9 / 15 (60.00%)		
occurrences (all)	9		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 March 2019	- extension of recruitment period (6 months) ; - modification of inclusion criteria : patients can be included up to 14 days after trauma, instead of 7 days

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported