Clinical trial results:
Prospective, monocentric study evaluating the efficacy of analgesia by continuous perineural catheter with Ropivacaine, in patients hospitalized for necrotizing angiodermatitis

Summary

EudraCT number	2013-002727-42
Trial protocol	FR
Global end of trial date	13 July 2018

Results information

Result version number	v1 (current)
This version publication date	20 September 2022
First version publication date	20 September 2022

Trial information

Trial identification

Sponsor protocol code	RC13_0252

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01964911
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU Nantes
Sponsor organisation address	5 allée de l'île Gloriette, Nantes, France, 44093
Public contact	RENAUD Sandrine, CHU de Nantes, 0033 0253482854, sandrine.renaud@chu-nantes.fr
Scientific contact	RENAUD Sandrine, CHU de Nantes, 0033 0253482854, sandrine.renaud@chu-nantes.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	06 July 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 July 2018
Global end of trial reached?	Yes
Global end of trial date	13 July 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of analgesic treatment by continuous perineural block with Ropivacaine, in patients hospitalized for necrotizing angiodermatitis.

Protection of trial subjects:

Increased monitoring of the block and its possible complications at the patient's bedside in hospital environment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 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	France: 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)	1
From 65 to 84 years	6
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

Recruitment took place in the Vascular Internal Medicine Department of Nantes University Hospital between 02/25/2014 and 07/13/2018.
The screening was carried out by the Department physician investigators on patients needing to be hospitalized for necrotizing angiodermatitis, being hyperalgesic on entry, either an EN at rest or on dressing > 5/10.

Pre-assignment

Screening details:

Inclusion criteria:
Men or women over the age of 18
Necrotizing angiodermatitis
Patients with EN collected 72 hours prior to catheter placement
Hyperalgesic on admission or failure of step 1 treatment with NE ≥ 5/10, and/or NE on dressing ≥ 5/10 at home, regardless of the premedication received.
OR poor tolerance of treatments

Pre-assignment period milestones

Number of subjects started	12
Number of subjects completed	12

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	Protocol treatment
Arm description: -	
Arm type	Protocol treatment
Investigational medicinal product name	ropivacain
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Perineural use

Dosage and administration details:

Ropivacain 0.2% (bag of 200cc solution for injection): 5mL/h, and possibility of bolus at the time of dressing by nurse of 5 mL

Number of subjects in period 1	Protocol treatment
Started	12
Completed	11
Not completed	1
Adverse event, non-fatal	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			
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			
arithmetic mean	81.5		
full range (min-max)	68 to 92	-	
Gender categorical Units: Subjects			
Female	8	8	
Male	4	4	

Subject analysis sets

Subject analysis set title	Primary outcome
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Only 13 patients were included out of the 30 planned but 1 didn't receive the treatment and 1 didn't have data concerning the baseline numerical pain scales. The statistical analysis is only descriptive given the small sample size (11 patients).

Reporting group values	Primary outcome		
Number of subjects	11		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			

Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years arithmetic mean full range (min-max)	 81.5 68 to 92		
Gender categorical Units: Subjects			
Female Male	8 4		

End points

End points reporting groups

Reporting group title	Protocol treatment
Reporting group description: -	
Subject analysis set title	Primary outcome
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Only 13 patients were included out of the 30 planned but 1 didn't receive the treatment and 1 didn't have data concerning the baseline numerical pain scales. The statistical analysis is only descriptive given the small sample size (11 patients).

Primary: Success defined by a decrease of at least 50% of one of 4 parameters related to the numerical scale of pain

End point title	Success defined by a decrease of at least 50% of one of 4 parameters related to the numerical scale of pain[1]

End point description:

End point type	Primary

End point timeframe:

Pain during the washout period (72 hours prior to treatment) was compared to pain during the first 72 hours on treatment.

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: The statistical analysis is only descriptive given the small sample size (11 patients).

End point values	Primary outcome			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: Patients				
Success	7			
Failure	4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

6 months concerning serious adverse events and 15 days concerning adverse events

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Protocol treatment

Reporting group description: -

Serious adverse events	Protocol treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 12 (41.67%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Vascular disorders			
Wound haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angiodermatitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Chest wall haematoma			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscle rigidity			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Dermo-hypodermitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			

subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Protocol treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 12 (33.33%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			

Angiodermatitis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Psychiatric disorders Confusional state subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Infections and infestations Pyelonephritis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Metabolism and nutrition disorders Malnutrition subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 January 2014	Modification concerning non-inclusion criterion related to allergies. The addition of the digital pain scale collection at 6 and 12 hours after catheter removal. Details of the examinations carried out before the start of treatment.
23 June 2014	Withdrawal of a non-inclusion criterion related to prohibited processing and modification of authorized processing accordingly. Modifications to the paragraph related to the description and justification of the therapeutic regimen.
14 November 2014	Modification of the Ropivacaine dosage (5 mL/h instead of 5 to 10 mL/h) and the duration of collection of adverse events.
21 March 2016	Change in supply management in Ropivacain and extension of the inclusion period.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported