



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 \geq 5/10, and/or NE on dressing \geq 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 | 81.5 | | |
| full range (min-max) | 68 to 92 | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 8 | | |
| Male | 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-hypodermatitis | | | |
| 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