



## Clinical trial results:

### The role of Qutenza (topical capsaicin 8%) in the treatment of chronic pain from critical ischaemia in patients with end stage renal failure

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2012-001586-32 |
| Trial protocol           | GB             |
| Global end of trial date | 01 July 2014   |

#### Results information

|                                   |                           |
|-----------------------------------|---------------------------|
| Result version number             | v1 (current)              |
| This version publication date     | 24 January 2019           |
| First version publication date    | 24 January 2019           |
| Summary attachment (see zip file) | Paper (Qutenza paper.pdf) |

#### Trial information

##### Trial identification

|                       |           |
|-----------------------|-----------|
| Sponsor protocol code | GN12RE072 |
|-----------------------|-----------|

##### Additional study identifiers

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

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | NHS Greater Glasgow and Clyde  |
| Sponsor organisation address | Dalnair Street, Glasgow, United Kingdom,   |
| Public contact               | Maureen Travers, NHS Greater Glasgow and Clyde, 44 1412116389, Maureen.Travers@ggc.scot.nhs.uk |
| Scientific contact           | Maureen Travers, NHS Greater Glasgow and Clyde, 44 1412116389, Maureen.Travers@ggc.scot.nhs.uk |

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:

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**Results analysis stage**

|  |                 |
|--|-----------------|
| Analysis stage                                       | Final           |
| Date of interim/final analysis                       | 15 October 2015 |
| Is this the analysis of the primary completion data? | No              |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 01 July 2014    |
| Was the trial ended prematurely?                     | No              |

Notes:

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**General information about the trial**

Main objective of the trial:

Does Qutenza (topical capsaicin 8%) reduce the chronic pain from digital critical ischaemia in patients with end stage renal failure?

Protection of trial subjects:

Single treatment with study drug. Direct follow-up and contact with clinical/ research team.

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 01 December 2012 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | No               |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United Kingdom: 22 |
| Worldwide total number of subjects   | 22                 |
| EEA total number of subjects         | 22                 |

Notes:

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**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)                      | 22 |
| From 65 to 84 years                       | 0  |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

Patient recruited between 30/4/13- 6/3/14

### Pre-assignment

Screening details:

Referral by clinical team. Screening completed by research team based on information from clinical team, patient and review of clinical notes

### Period 1

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

Blinding implementation details:

NA

### Arms

|           |           |
|-----------|-----------|
| Arm title | Treatment |
|-----------|-----------|

Arm description:

Qutenza-single application

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Qutenza            |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Transdermal system |
| Routes of administration               | Transdermal use    |

Dosage and administration details:

Patch- single application

| Number of subjects in period 1 | Treatment |
|--------------------------------|-----------|
| Started                        | 22        |
| Completed                      | 20        |
| Not completed                  | 2         |
| Consent withdrawn by subject   | 1         |
| Protocol deviation             | 1         |

## Baseline characteristics

## End points

### End points reporting groups

|   |                            |
|---|----------------------------|
| Reporting group title   | Treatment                  |
| Reporting group description:<br>Qutenza-single application                |                            |
| Subject analysis set title  | Painful critical ischaemia |
| Subject analysis set type   | Intention-to-treat         |
| Subject analysis set description:<br>ESRD with painful critical ischaemia |                            |

### Primary: Difference in VAS at 12 weeks

|                        |  |
|------------------------|--|
| End point title        | Difference in VAS at 12 weeks <sup>[1]</sup> |
| End point description: |  |

|                                  |         |
|----------------------------------|---------|
| End point type                   | Primary |
| End point timeframe:<br>12 weeks |         |

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: Retrospective documentation

|                             |                            |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| <b>End point values</b>     | Painful critical ischaemia |  |  |  |
| Subject group type          | Subject analysis set       |  |  |  |
| Number of subjects analysed |                            |  |  |  |
| Units: Pain score           | 20                         |  |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

12 weeks

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

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### Dictionary used

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|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

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|                    |      |
|--------------------|------|
| Dictionary version | 10.0 |
|--------------------|------|

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

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Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Retrospective documentation

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### 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.

|                     |
|---------------------|
| Retrospective entry |
|---------------------|

Notes: