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:

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:

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:

Population of trial subjects

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:

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: Qutenza-single application	
Subject analysis set title	Painful critical ischaemia
Subject analysis set type	Intention-to-treat
Subject analysis set description: ESRD with painful critical ischaemia	

Primary: Difference in VAS at 12 weeks

End point title	Difference in VAS at 12 weeks[1]
End point description:	
End point type	Primary
End point timeframe: 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

End point values	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

Adverse events information[1]	
Timeframe for reporting adverse events: 12 weeks	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0

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

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

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: