Clinical trial results:
Heat-, Cold-, and Mechanical Painthresholds under exposition of high dose topical Capsaicin

Summary

EudraCT number	2013-002546-36
Trial protocol	AT
Global end of trial date	07 December 2020

Results information

Result version number	v1 (current)
This version publication date	15 October 2022
First version publication date	15 October 2022

Trial information

Trial identification

Sponsor protocol code	CAPS2

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	MedUni Wien
Sponsor organisation address	Waehringer Guertel 18-22, Vienna, Austria, 1090
Public contact	Investigator, MedUni Wien, Universitätsklinik für Anästhesie, Allgemeine Intensivmedizin und Schmerztherapie, 0043 1404004139,
Scientific contact	Investigator, MedUni Wien, Universitätsklinik für Anästhesie, Allgemeine Intensivmedizin und Schmerztherapie, 0043 1404004139,

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	17 April 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 April 2014
Global end of trial reached?	Yes
Global end of trial date	07 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determination of heat-painthreshold under exposition of high-dose Capsaicin for 60 minutes

Protection of trial subjects:

Inclusion criteria were unharmed, unscarred skin on forearms with no neurological malfunction. Exclusion criteria were: pregnancy, breast-feeding, use of capsaicin in the areas of the study treatment or regular use of analgesics within the previous three months as well as any contraindication against at least one of the drug medications, and drug addiction.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 August 2013
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	Austria: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

20 volunteers (10 women and 10 men) were enrolled in the study. There mean age was 25 years, range: 21 to 29. All were of white ethnic origin. All the 20 study subjects received patch treatments, completed the study, and were included in the statistical analysis of outcome

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous patch
Routes of administration	Topical use

Dosage and administration details:

0% 1x

Arm title	Qutenza

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Qutenza
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous patch
Routes of administration	Epicutaneous use

Dosage and administration details:

part of one high-concentration (640 µg/cm2 [8%]) capsaicin patch (QutenzaTM, ASTELLAS PHARMA, Tokyo, Japan) of 9 cm² (3x3 cm) was applied for 60 minutes to the distal left or right forearm

Number of subjects in period 1	Placebo	Qutenza
Started	10	10
Completed	10	10

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	20	20	
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)	20	20	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	10	10	
Male	10	10	

Subject analysis sets

Subject analysis set title	Pain threshold
Subject analysis set type	Full analysis

Subject analysis set description:

The primary endpoint was the mean heat pain threshold (HPTTSA) at 60 minutes recorded by each participant separately for each of the two application sites.

Reporting group values	Pain threshold		
Number of subjects	20		
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)	20		
From 65-84 years	0		
85 years and over	0		

Gender categorical Units: Subjects			
Female	10		
Male	10		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Qutenza
Reporting group description: -	
Subject analysis set title	Pain threshold
Subject analysis set type	Full analysis
Subject analysis set description:	
The primary endpoint was the mean heat pain threshold (HPTTSA) at 60 minutes recorded by each participant separately for each of the two application sites.	

Primary: heat painthreshold under exposition of high-dose capsaicin for 60 minutes

End point title	heat painthreshold under exposition of high-dose capsaicin for 60 minutes
End point description:	
End point type	Primary
End point timeframe:	
60 minutes	

End point values	Placebo	Qutenza		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: temperature				
arithmetic mean (standard deviation)	46.4 (± 2.7)	35.3 (± 4.8)		

Statistical analyses

Statistical analysis title	ANOVA
Comparison groups	Placebo v Qutenza
Number of subjects included in analysis	20
Analysis specification	Post-hoc
Analysis type	non-inferiority
P-value	< 5
Method	ANOVA

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 19.11.2013-11.04.2014	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1

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: no non-serious adverse events

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

None reported