Clinical trial results:
CAPSAICIN PATCH 8% FOR THE TREATMENT OF PERSISTENT PAIN AFTER INGUINAL HERNIOTOMY

Summary

EudraCT number	2012-001540-22
Trial protocol	DK
Global end of trial date	30 September 2013

Results information

Result version number	v1 (current)
This version publication date	26 August 2016
First version publication date	26 August 2016
Summary attachment (see zip file)	A Capsaicin (8%) Patch in the Treatment of Severe Persistent Inguinal Postherniorrhaphy Pain: A Randomized, Double-Blind, Placebo-Controlled Trial (CapsaicinPublikation.pdf)

Trial information

Trial identification

Sponsor protocol code	76122012

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, copenhagen, Denmark,
Public contact	Tværfagligt smertecenter, Rigshospitalet, 45 35457612,
Scientific contact	Tværfagligt smertecenter, Rigshospitalet, 45 35457612,

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	30 September 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 September 2013
Global end of trial reached?	Yes
Global end of trial date	30 September 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

to investigate analgesic and sensory effects of a capsaicin patch (Qutenza) in patients with severe postherniotomy pain and sensory abnormalities in the skin.

Protection of trial subjects:

Patients were pre-treated with a topical local anesthetic cream (EMLA, lidocaine/prilocaine 25 mg/25 g, AstraZeneca AB, Sweden) 60 min before capsaicin patch application.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 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	Denmark: 46
Worldwide total number of subjects	46
EEA total number of subjects	46

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)	31
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients eligible in the study were referred to the Multidisciplinary Pain Center by a surgeon or a general practitioner and written informed consent was obtained from all patients. Patients were $18 years with severe unilateral persistent inguinal postherniorrhaphy pain (numerical rating scale [NRS, 0–10] $ 5) for more than 6 months.

Pre-assignment

Screening details:

Patients eligible in the study were referred to the Multidisciplinary Pain Center by a surgeon or a general practitioner and written informed consent was obtained from all patients. Patients were $18 years with severe unilateral persistent inguinal postherniorrhaphy pain (numerical rating scale [NRS, 0–10] $ 5) for more than 6 months.

Period 1

Period 1 title	3 months (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	capsaicin group

Arm description: -

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

Dosage and administration details:

capsaicin patch (capsaicin 640 mg/cm2, 8% w/w; Astellas Pharma Europe B.V., Leiderdorp, The Netherlands)

Arm title	placebo group

Arm description: -

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

Dosage and administration details:

inactive placebo patch

Number of subjects in period 1	capsaicin group	placebo group
Started	24	22
Completed	22	20
Not completed	2	2
Lost to follow-up	2	2

Baseline characteristics

End points

End points reporting groups

Reporting group title	capsaicin group
Reporting group description: -	
Reporting group title	placebo group
Reporting group description: -	
Subject analysis set title	placebo group
Subject analysis set type	Intention-to-treat
Subject analysis set description: inactive placebo patch	
Subject analysis set title	capsaicin group
Subject analysis set type	Intention-to-treat
Subject analysis set description: capsaicin group	

Primary: The primary outcome was comparisons of SPIDs between capsaicin and placebo treatments at 1, 2 and 3 months after patch application

End point title	The primary outcome was comparisons of SPIDs between capsaicin and placebo treatments at 1, 2 and 3 months after patch application
End point description:	
End point type	Primary
End point timeframe: The primary outcome was comparisons of SPIDs between capsaicin and placebo treatments at 1, 2 and 3 months after patch application	

End point values	placebo group	capsaicin group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	22		
Units: NRS				
arithmetic mean (confidence interval 95%)	-0.2 (-3.8 to 3.4)	4.8 (1.4 to 8.2)		

Statistical analyses

Statistical analysis title	Linear regression analyses
Comparison groups	capsaicin group v placebo group

Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Regression, Linear

Adverse events

Adverse events information

Timeframe for reporting adverse events:

At the clinical visit 1month after patch application patients were asked to report if they had experienced application site skin reactions (erythema, pain, burning sensation) or any other adverse events

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	Capsaicin group

Reporting group description: -

Serious adverse events	Capsaicin group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Capsaicin group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 22 (77.27%)		
Skin and subcutaneous tissue disorders			
Erythema			
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 22 (40.91%)		
occurrences (all)	9		
pain	Additional description: pain during patch application		
alternative assessment type: Non-systematic			
subjects affected / exposed	12 / 22 (54.55%)		
occurrences (all)	12		
Burning sensation	Additional description: burning sensation during patch application		
subjects affected / exposed	12 / 22 (54.55%)		
occurrences (all)	12		

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