# 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