TRIAL INFORMATION

Full title of the trial:

Full title of the trial	Topical lidocaine: Predictors of response in peripheral nerve damage

Trial Identifiers:

EudraCT no.	2009-016038-29
Sponsor protocol Code	LIDO-2009
ISRCTN no.	-
Clinicaltrial.gov NCT no.	-
WHO Trial no./Universal Reference no. (UTN)	-

Sponsor:

Organisation name	Aarhus University, Danish Pain Research Center
Street Address	Palle-Juul Jensens Boulevard 165
Post Code	8200
Town/city	Aarhus N
Country	Denmark

Contact points – Scientific contact point:

Name of organisation	Aarhus University, Danish Pain Research Center

Functional name of contact	Nanna Brix Finnerup
Telephone number	+4578463382
Email address	finnerup@clin.au.dk

Contact points – Public contact point:

Name of organisation	Aarhus University, Danish Pain Research Center	
Functional name of contact	Nanna Brix Finnerup	
Telephone number	+4578463382	
Email address	finnerup@clin.au.dk	

OBS! Scientific and public contact point may be the same

Paediatric regulatory details:

Is the trial part of a Paediatric Investigation Plan (PIP)	No
EMA Paediatric Investigation Plan	No
Does the article 45 in Regulation 1901/2006 apply to this trial?	No
Does the article 46 in Regulation 1901/2006 apply to this trial?	No

Result analysis stage:

Analysis stage	Final
Date of interim/final analysis	March 2011
Primary completion date reached?	Yes
Primary completion date	February 2011
Global end of trial reached?	Yes
Date of global end of trial	February 2011

Was the trial prematurely ended	No

General information about the trial:

Main objectives of the trial	The primary purpose is to study the predictive value of preserved nociceptors and large afferent fibers and dynamic mechanical allodynia on the effect of lidocaine patch (Versatis 5% medicated plaster). The primary outcome measure is the predictive role for these measures for obtaining a response to lidocaine. A responder is defined as a person with at least a 2-point reduction in median pain intensity (measured from a baseline week to the last week of treatment.
Actual date of start of recruitment	June 2010
Long term follow-up planned?	No

Independent Data-monitoring Committee involvement?	No
Protection of subjects (A description of the actions taken to protect subjects)	Only investigators were aware of personal information like cpr number, name and address. Followed standard requirement regarding safety
Background therapy (Details such as the dosage and frequency, plus any other relevant information should be captured here)	Concomitant systemic analgesics were allowed in a constant and unchanged dose during the trial. Paracetamol up to 3 g/day was allowed as rescue Medication.
Evidence for comparison(s) (Provide a rationale for the use of the comparators used in the trial. If the evidence in the context of the trial, provide the details)	No comparators used

Population of trial subjects:

Choose country	Denmark

Subjects per country:

Trial country	Denmark					
Planned number of subjects	28					
Actual number of subjects	24					

Age of subjects:

	Number of subjects
Between 18 years and above	24

SUBJECT DISPOSITION

Recruitment details (Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types and location (e.g. medical clinic))	Twenty-four patients with peripheral neuropathic pain due to traumatic or postsurgical peripheral nerve injury who attended the Neuropathic Pain Clinic, Department of Neurology, Aarhus University Hospital, were recruited between June 2010 and February 2011

Pre-assignment period:

		Number of subjects
STARTED		24
COMPLETED (at least 4 weeks)		21

COMPLETED 12 weeks		10
Reason for non-completion		Adverse event, N=2 Declined to participate, N=1

OBS! You can add as many milestones as you want. A descriptive title for each row is required.

Period table (**OBS!** Complete a period table for each period you wish to report. Provide a descriptive title for each reported period)

Title (If you only have one period, your default title should be "overall period")	**Active treatment**
Baseline period	Yes, one week
Allocation method	Not applicable (Not controlled)
Blinding used	Not blinded

Arms

Are the arm mutually exclusive? (Only answer no, if the subjects are present in more than one arm in a period. If the arms are not mutually exclusive, the number of subjects in the period, will not be calculated automatically)	Only one arm

Arm table (**OBS!** Complete an Arm Table for each arm you wish to report. Provide a descriptive title for each reported arm)

Arm Title	Active treatment
Arm description (provide more information)	Lidocaine (5%) medicated patches were used (Versatis, Gr€unenthal GmbH, Aachen, Germany) in a 12-week treatment period. Due to ethical issues we included a control visit after 4 weeks of treatment (where an effect should be evident), and patients who did not report a beneficial effect in their pain diary on a pain relief scale, were allowed to discontinue the study at that time
Arm type	Experimental Lidocaine (5%) medicated patches
	Number of subjects

STARTED	June 2010	
COMPLETED	February 2011	
		Number of subjects
Reason not completed	Adverse events (not serious), N=2 Declined to participate, N=1	3

Product used: (**OBS!** Filled out for each arm reported)

IMP Name	Versatis 5% medicated plaster
IMP Code	PL21727/0016
Other names?	No
Route of administration	Cutaneous use
Pharmaceutical form	Patch
Dosage and administration details	5% (W/W)

BASELINE CHARACTERISTICS

Age (Continuous)	
Units	Years
Central tendency type/Measure type	Mean

Dispersion type	Standard deviation				
Value of measure type in Reporting group 1=Total					
47.6 (13.5)					

Gender	Number			
	Number of subjects Reporting group 1=Total			
Female	**12**			
Male	**12**			

END POINTS

End point title	Predictive role of dynamic mechanical allodynia on responding
Countable	Countable
If measurable is chosen, enter measurable unit	Number of responders/total numbers
End point type	Primary

End point description	Number of patients who responds to lidocaine patch defined as a person with at least a 2-point reduction in median pain intensity
End point time frame	From the baseline week to the last week of treatment (4-12 weeks)

Value of measure type in Reporting group 1=Total	Responders among patients with dynamic mechanical allodynia	Responders among patients without dynamic mechanical allodynia			
8/20	6/16	2/4			

Statistical analysis title	Predictor 1	
Comparison group	Patients with and without dynamic mechanical allodynia	
Number of subjects in this analysis	20 (16 with dynamic mechanical allodynia, 4 without)	
Analysis specification	Pre-specified	
Analysis type	Superior	
Analysis type comment	Only patients who completed the study on all efficacy measures were analysed (n=20) (one did not return pain diary)	
Statistical hypothesis test		
P-value	P=1.0	
Method	Fisher's exact test	

End point title	Predictive role of normal small sensory function
Countable	Countable
If measurable is chosen, enter measurable unit	Number of responders/total numbers
End point type	Primary

End point description	Number of patients who responds to lidocaine patch defined as a person with at least a 2-point reduction in median pain intensity
End point time frame	From the baseline week to the last week of treatment (4-12 weeks)

Value of measure type in Reporting group 1=Total	Responders among patients with normal cold sensation	Responders among patients with normal cold sensation			
8/20	8/11	0/9			

Statistical analysis title	Predictor 2	
Comparison group	Patients with and without normal cold sensation	
Number of subjects in this analysis	20 (11 with normal cold sensation dynamic mechanical allodynia, 9 without)	
Analysis specification	Pre-specified	
Analysis type	Superior	
Analysis type comment	Only patients who completed the study on all efficacy measures were analysed (n=20) (one did not return pain diary)	
Statistical hypothesis test		
P-value	P=0.001	
Method	Fisher's exact test	

ADVERSE EVENTS

Time frame for adverse event reporting	Whole study
Assessment type	Non-systematic

Adverse Events Reporting group:

Here you can either use arm from baseline period as reporting groups, by ticking a box - or create new reporting groups:

Subjects exposed (Enter the number of subject in this reporting group exposed to the treatment)	24
Number of subjects affected by serious adverse events	0
Number of subjects drop out because of adverse effects	2
Number of deaths (all causes)	0
Number of deaths resulting from adverse events	0

MORE INFORMATION

Global substantial protocol amendments: None

Global interruptions and restarts: None

Limitations and caveats:

Limitations and caveats that apply to the results	**Please refer to published paper**

Online references:

PubMED identifier (PMID) and add link	PMID: 23653369 **Link: https://onlinelibrary.wiley.com/doi/full/10.1002/mus.23794**