Clinical trial results:
ROLE DES NEO-ARTICULATIONS TRANSVERSO-SACREES OU TRANSVERSO-ILIAQUES (ATLS) DANS LES LOMBALGIES CHRONIQUES : ETUDE PROSPECTIVE MULTICENTRIQUE RANDOMISEE EN DOUBLE AVEUGLE DE L'EFFICACITE DES INFILTRATIONS CORTISONEES VERSUS INFILTRATIONS DE SERUM PHYSIOLOGIQUE

Summary

EudraCT number	2010-019626-14
Trial protocol	FR
Global end of trial date	05 February 2015

Results information

Result version number	v1 (current)
This version publication date	01 May 2021
First version publication date	01 May 2021

Trial information

Trial identification

Sponsor protocol code	BRD 10/03-N

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01206699
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU de Nantes
Sponsor organisation address	5 allée de l'île Gloriette, Nantes, France, 44000
Public contact	Dr Glémarec J, CHU de Nantes, 33 0240084824, bp-prom-regl@chu-nantes.fr
Scientific contact	Dr Glémarec J, CHU de Nantes, 33 0240084824, bp-prom-regl@chu-nantes.fr

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	05 August 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 February 2015
Global end of trial reached?	Yes
Global end of trial date	05 February 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Le but de cette étude est de montrer, en les traitant par une infiltration de corticoïde, que certaines lombalgies chroniques peuvent s'expliquer par la présence d'une néo-articulation.

Protection of trial subjects:

À 12 semaines l'aveugle était ouvert de manière à proposer au patient restant douloureux et ayant reçu le sérum physiologique, une infiltration de cortivazol en ouvert sous scanner. Il leur était proposé un suivi hors protocole à sept jours, 4 semaines et 12 semaines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 December 2010
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	France: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	14
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study concerns adults (age > or = 18 years) suffering from lateralized low back pain on the side of the malformation, evolving for more than three months and resistant to analgesics and non-steroidal anti-inflammatory drugs.

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	Group 1

Arm description:

Anaesthetic block (1 ml of lidocaine 1%) then immediately 1.5 ml of saline solution is injected.

Arm type	Placebo
Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intraarticular use

Dosage and administration details:

It is administered as a single injection. The anesthesia is done shot by shot with lidocaine. When the needle is intra-articular an anesthetic block is made with 1ml of lidocaine. The needle is left in place followed by 1.5 ml of
saline solution injected. Saline solution comes in 10 cc ampoules which are sterilely withdrawn in a graduated syringe.

Arm title	Group 2

Arm description:

Anaesthetic block (1 ml of lidocaine 1%) then immediately 1.5 ml of corticosteroid is injected.

Arm type	Experimental
Investigational medicinal product name	Corticosteroid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intraarticular use

Dosage and administration details:

It is administered as a single injection. The anesthesia is done shot by shot with lidocaine. When the needle is intra-articular an anesthetic block is made with 1ml of lidocaine. The needle is left in place followed by 1.5 ml of
corticosteroid injected. The corticosteroid comes in a pre-filled syringe.

Number of subjects in period 1	Group 1	Group 2
Started	8	7
Completed	8	7

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	15	15	
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)	14	14	
From 65-84 years	1	1	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	8	8	
Male	7	7	

End points

End points reporting groups	
Reporting group title	Group 1
Reporting group description:	
Anaesthetic block (1 ml of lidocaine 1%) then immediately 1.5 ml of saline solution is injected.	
Reporting group title	Group 2
Reporting group description:	
Anaesthetic block (1 ml of lidocaine 1%) then immediately 1.5 ml of corticosteroid is injected.	

Primary: VAS	
End point title	VAS
End point description:	
Difference of the mean VAS of the 24 hours before the infiltration and the mean VAS of the 24 hours before the visit at Week 4.	
End point type	Primary
End point timeframe:	
Week 4	

End point values	Group 1	Group 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	7		
Units: NA	8	7		

Statistical analyses

Statistical analysis title	Mean 24-hour VAS pain score
Statistical analysis description:	
The primary outcome measure was the difference in the mean 24-hour VAS pain score from baseline to 4 weeks after the injection. Secondary outcome measures were compared using either the non-parametric Wilcoxon test or, for comparisons of baseline values to week 4 or week 12 values in the two treatment groups pooled, the Wilcoxon test for paired data.	
Comparison groups	Group 2 v Group 1
Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Mean difference (net)
Point estimate	3

Confidence interval	
level	90 %
sides	2-sided
lower limit	1
upper limit	3
Variability estimate	Standard error of the mean

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Overall	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	NA

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 serious adverse events were reported.

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